CANCER THERAPY EVALUATION PROGRAM, NATIONAL CANCER INSTITUTE

Protocol Authorization and Tracking System

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APPLICATION USER'S GUIDE

BUILDING THE FUTURE ™ TOGETHER

PRODUCED BY CAPITAL TECHNOLOGY INFORMATION SERVICES, INC.

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The date on the cover of this user's guide reflects the document release date, which may differ from the software release date.

Information within this user's guide is current as of the date of publication. Software changes and enhancements incorporated into the system after the publication date will be reflected in future releases of the guide.

This user's guide contains sample queries and screen examples taken from the CTEP-ESYS development database. If you are using the CTEP-ESYS production database, your query and screen data may differ from that depicted in this guide.

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Section 1 Before You Begin

Introduction

The procedures described here also apply to Letters of Intent and Concept Reviews, unless otherwise noted. Screens may vary from one module to the next.

System Overview

Capital Technology Information Services, Inc. (CTIS) developed the Protocol Authorization and Tracking System (PATS) for the Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute (NCI).

PATS, an Operation System of the CTEP - Enterprise System (ESYS), provides the ability to enter, modify, and retrieve protocol data. It allows CTEP users to manage and monitor protocol processes, generate reports, and create correspondence. (For additional information regarding the CTEP-ESYS, please refer to the CTEP-ESYS Supplement.) With this system, PATS can:

- Abstract administrative protocol information.
- Track administrative data.
- Manage administrative protocol information throughout the protocol's lifecycle.
- Generate reports.

CTEP and CTIS welcome your comments and suggestions and will make every effort to incorporate useful suggestions into the procedures, software, and documentation.

What This Guide Provides

The PATS User's Guide provides detailed descriptions of the PATS features used to enter, modify, and retrieve protocol data. In PATS, these features are located on a number of task-specific screens.

This guide presents each screen separately along with an illustration of the screen and the menu path. Following a description of the screen, you will find step-by-step procedures on how to enter information (or data elements) into the system. These instructions proceed in the order you would normally encounter the fields.

An appendix provides a detailed definition of each data field on each screen. Where the data field contains a drop-down list of values (LOV), you will find a listing of those values and a description of each value. Some LOVs contain very large number entries that vary frequently. In these cases, the LOVS are not enumerated individually.

Conventions Used in this Guide

As a PATS user, you should have a working knowledge of Microsoft Windows. This guide uses a number of type and style conventions to communicate specific information easily. The following table details these conventions.

CONVENTION	MEANING
Bold	Indicates commands, menus, check boxes, and option buttons. This includes menu commands, toolbar command buttons, command buttons within a screen, and keys on your keyboard.
Sans serif font	Indicates a message displayed by the system and specific information you must enter into a field on the screen.
Click	Point the mouse to a named item and press the left mouse button once.
Double-Click	Point the mouse to a named item and press on the left mouse button twice.
Enter	Type a value in the field.
Select	Highlight an item in a list.
Choose	Activate the named command.

System Requirements

PATS runs on the MS Windows 95 or 98 operating systems. The following represents the minimum equipment configuration needed. Your system may, of course, exceed the minimum requirements.

- An IBM®-compatible personal computer with a Pentium or higher processor.
- A hard disk with 100 Megabytes (MB) of free space.
- 128 MB of Random Access Memory (RAM).
- A Microsoft Mouse or other compatible pointing device.
- An EGA, VGA, or compatible display - VGA or higher recommended.
- Microsoft Windows 95, 98, or NT

User accounts can be obtained by contacting the CTEP Help Desk via electronic mail at ctephelp@ctep.nci.nih.gov.

Setting the Screen Resolution

Screen resolution is a measure of how many pixels per inch make up the image you see on your computer monitor. The greater the number of pixels, the higher the quality of the image.

In order to view PATS properly, it is important to set your screen monitor resolution to 1152 x 864. This means the image contains 1152 pixels in the horizontal direction, 864 in the vertical. You also need to set your computer to display small fonts.

When you enter the application through the CTEP Enterprise System (CTEP-ESYS) Front Panel, the system automatically sets the screen resolution. It will reset the screen to its original resolution when you exit the application through the CTEP-ESYS Front Panel.

These steps guide you through setting the screen resolution.

1. Choose the **Control Panel** option under **Settings** on the **Start** menu.
2. Choose **Display**.
3. Move to the Settings tab.
4. Set the resolution under Desktop Area.
5. Set the fonts with the drop-down list under Font Size.
6. Click **OK** to accept your settings.

If your screen monitor resolution setting is already set at 1152 x 864, it requires no change.

Getting Help

PATS has several methods to assist you in working through questions.

- The first method consists of the error messages provided to notify you of an issue with the function you just performed. Information within the error message helps you to isolate and correct the issue.
- The second method is to review this user guide. It provides specific instructions for each function of this application.
- The third method is to contact the CTEP Help Desk by electronic mail at ctephelp@ctisinc.com

Further Information

Please refer to the following resources for additional information:

- NCI CTEP Home Page: http://ctep.info.nih.gov
- NCI CTEP Enterprise System (CTEP-ESYS) User's Guide
- NCI CTEP Address Maintenance Module (AMM) User's Guide
- NCI CTEP Address Query Module (AQM) User's Guide
- Document Naming, Numbering, and Placement Quick Reference Guide

To obtain further information, please contact the CTEP Help Desk by electronic mail at ctephelp@ctisinc.com or call 301/948-3033.

Section 2 The Protocol Authorization Tracking System

Starting the System

Starting the System

In order to begin using PATS, it is necessary to have Developer 2000 software and the Enterprise Control Panel icon installed on your desktop. The production icon is shown in Figure 1.

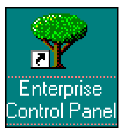


Figure 1 Enterprise Control Panel Icon.

Once you double-click on this icon, a Logon dialog box (shown in Figure 2) appears.

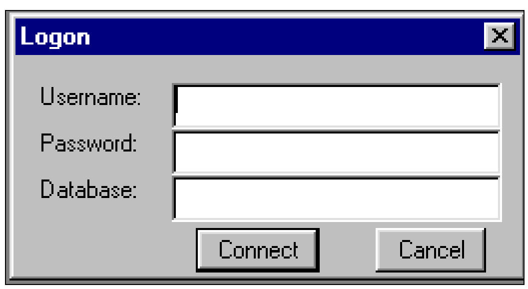


Figure 2 Logon Dialog Box

Logging On

In the Logon dialog box, enter your user name and system password in the Username and the Password fields. Enter your database location (CTEPESYSPROD) in the Database field. Then click **Connect**.

If you do not use the correct username, password, and database location, you will receive an error message. Re-enter the username, password, and database information and attempt to bring up the application again. If you continue to have problems or do not have the appropriate information, please e-mail ctephelp@ctisinc.com, listed as CTIS Help Account in the Global Address Listing (GAL) in Microsoft Outlook.

The CTEP Enterprise Front Panel

When you have successfully logged on, the CTEP Enterprise System Front Panel screen (shown in Figure 3) opens.

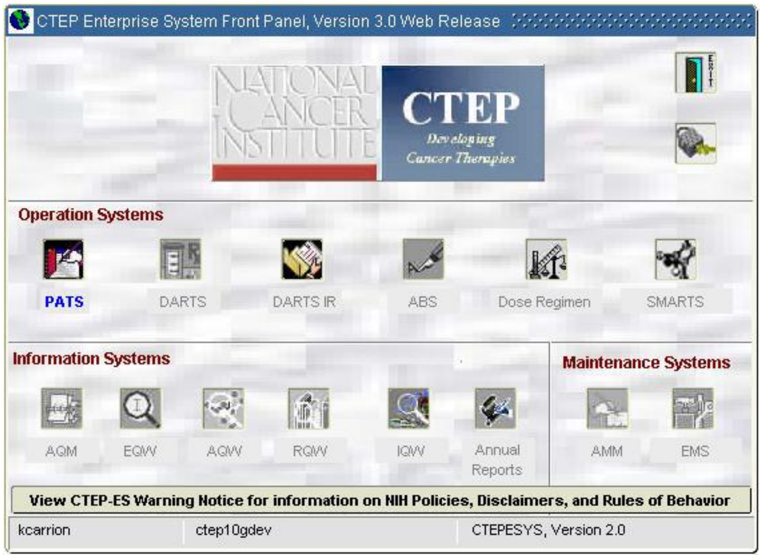


Figure 3 The CTEP Enterprise System Front Panel

The CTEP Enterprise System Front Panel provides a single place of entry for all of the available Enterprise systems. However, not all users have access to all systems (for example, DARTS, Dose Regimen, CDU Reports, EMS). Only those systems with bold icons are accessible to your logon privileges. All other icons are dimmed.

To access PATS from this panel, double-click on the **PATS** icon. To exit this screen, click the **Exit** icon located in the top right corner of this screen.

The CTEP PATS Screen

Once you have entered the appropriate user name, password, and database location, the first screen to appear is the PATS screen (shown in Figure 4) that identifies the application and presents the system menus.

Figure 4 Protocol Authorization and Tracking System Screen

The CTEP Protocol Authorization and Tracking System screen provides access to all features within the PATS application. The menu bar on this screen is the central point of navigation for all other PATS screens. You will access all PATS screens from this menu bar. To select a screen, you must first close all other open PATS screens, and return to the CTEP Protocol Authorization and Tracking System screen. For detailed directions about opening specific screens, refer to the section of this guide that describes that function or task.

PATS Screen Features

Screen Description

PATS screens contain a menu bar, toolbar, work area, and status bar. Except for the CTEP Protocol Authorization and Tracking System screen, all PATS screens have the same menu bar and toolbar. The commands contained in the menu bar and toolbar are the same for all screens and are described later in this section.

The work area contains a collection of text boxes, command buttons, check boxes, option boxes, and other features used to record information. Some of these features are visibly divided into named blocks of information or group boxes. Detailed descriptions of individual features are found later in this section.

The status bar displays information about the feature currently in use.

Features at the bottom of the screen may be blocked from view by the Windows taskbar. The taskbar is distinguished by the **Start** command button located at the lower left corner of the screen. If you can see the **Start** command, then you will want to hide the Windows taskbar in order to see the features at the bottom of the PATS screens.

Steps to Hide the Taskbar

Follow these steps to hide the Windows taskbar.

1. Right-click the Windows taskbar to open the **Taskbar** menu.
2. Click **Properties**.
3. Click the **Taskbar Options** tab.
4. Select the **Auto hide** check box.
5. Click **Apply**.
6. Click **OK**.

The taskbar disappears to reveal the features at the bottom of the screen. Anytime you want to use a command located on the taskbar, move the pointer to the bottom of the screen until the taskbar reappears.

Menu Bar Description

The menu bar at the top of a screen provides a collection of named menus containing commands for specific functions. When you select a named menu, the list of commands appears. If a command appears dimmed, it is unavailable for use. Each of the menu commands is described below.

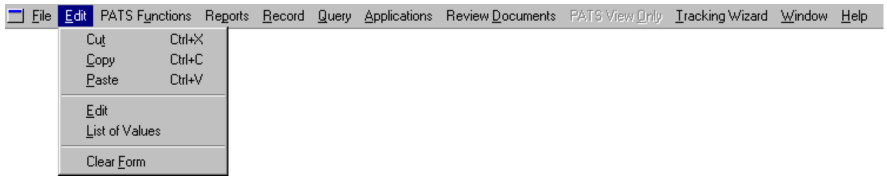
File Menu

The **File** menu provides commands that apply to a currently open file.

- **Save:** Saves the work in progress.
- **Print:** Displays the Print dialog box. You can select the printer you want to use, change the printer's functional properties, and select the number of copies for printing. After making any adjustments, click **OK**. The currently displayed screen will print.
- **Exit:** Closes the currently displayed screen. The screen opened prior to the current screen will appear. Note that the query function must be turned off before PATS will allow you to exit a screen.

Edit Menu

The **Edit** menu provides commands that affect the contents of the text box where you have positioned the insertion point.



- **Cut:** Removes highlighted text that is then available to paste elsewhere.
- **Copy:** Makes a copy of the highlighted text available to paste elsewhere.
- **Paste:** Allows you to position text you have cut or copied wherever you have set the insertion point.
- **Edit:** Allows you to search for and edit specific text.
- **List of Values:** Provides an alternate method to open the List of Values for a text box. You must first set the insertion point in the text box.
- **Clear Form:** Removes all the information from the text boxes in the current form.

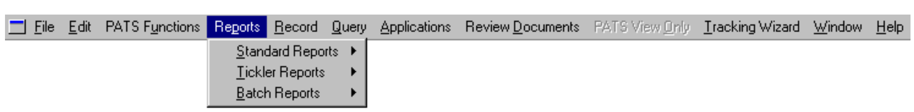
  Limitations to the **Clear Form** command do exist. On screens where all the information collected is contained within a single record, **Clear Form** will not function when mandatory text boxes remain empty. If this happens, use the **Clear Record** command, described under Record Menu.

PATS Functions Menu

The **PATS Functions** menu allows you to select all the commands that access functions specific to using the PATS application. Refer to the sections of this manual that provide detailed descriptions for each of these functions.

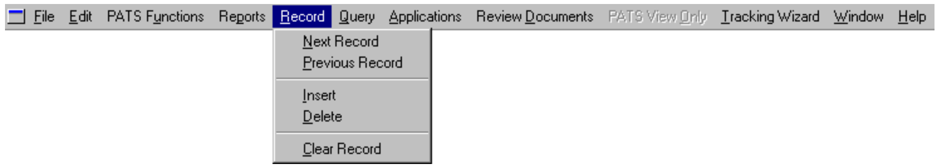
Reports Menu

The **Reports** menu provides access to all the reports you can generate through the PATS application. Refer to the Reports section of this manual for detailed directions on using these menu commands.



Record Menu

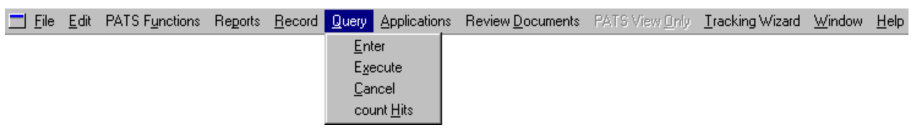
A record is a collection of associated information contained in one or more text boxes. The **Record** menu provides commands that apply to individual records. When you apply a command to a record containing information on which other records depend, the command will be applied to all the dependent records as well.



- **Next Record:** Displays the record immediately following the currently shown record.
- **Previous:** Displays the record immediately preceding the currently shown record.
- **Insert:** Creates a blank record at the location of the insertion point. You can then enter an additional record at the location.
- **Delete:** Deletes the record at the insertion point location.
- **Clear Record:** Clears the record at the insertion point location. (See **Clear Form**.)

Query

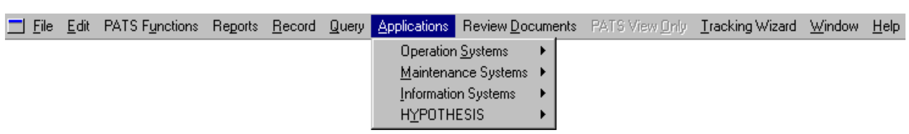
The **Query** menu provides commands used to search the database for a specific record, which, when found, automatically populates in the appropriate text boxes.



- **Enter:** Turns on the query function and allows you to select a text box. You can then enter criteria to query. The criteria can consist of a single letter or a close approximation of the spelling for the desired record.
- **Execute:** Initiates a query on previously entered criteria. If no criterion exist, then the first available record will appear. If the criterion consists of a single letter, then the first record starting with that letter will appear.
- **Cancel:** Turns off the query function and cancels a query in progress. Remember that you must turn off the query function before exiting a screen.

Applications Menu

The **Applications** menu allows you to access other CTEP applications. If you have the authorization to do so, you can use these applications.



PATS View Only

For future implementation.

Tracking Wizard

The **Tracking Wizard** menu accesses the Tracking Wizard screen from which you can print out reports documenting the document review process. Refer to Page 49 for more details.

Window

The **Window** menu allows you to set up your windows to suit the way you want to use the applications you access on a regular basis. Refer to your Microsoft Windows manual for detailed directions on using these features.

Help

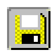
This **Help** menu accesses copyright information regarding the PATS system. Future versions will also allow you to access On-line Help.

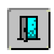
Toolbar Description

The PATS screen toolbar (shown in Figure 5) consists of 14 command buttons from which you can select common operations. All of the command buttons repeat the same commands found on the menu bar. Refer to the menu bar descriptions for additional details.

Figure 5 The PATS Screen Toolbar

When you position the pointer over a command button, the button name appears in a yellow rectangle to the right of the toolbar. The following table describes the individual command buttons.

 **Save –** Saves the work in progress.

 **Exit –** Ends the task in progress and exits the screen.

 **Print** – Prints the screen or report.

 **Edit –** Allows you to search for and edit specific text.

 **Enter Query –** Activates the query function, allowing you to select a text box and enter query criteria.

 **Execute Query –** Initiates a previously entered query.

 **Insert –** Allows you to hide a selected record and open the text box to insert another record.

 **Delete –** Deletes the selected record.

 **Clear Record –** Clears the current record.

 **Clear Form –** Clears the current form.

 **Previous Record –** Displays the previous record.

 **Next Record –** Displays the next record.

Entering Data

You will insert the majority of your information into text boxes. A text box with an identifying name appearing in blue bold type indicates that the requested information is mandatory. If you leave one or more of the mandatory text boxes empty, you will be unable to commit or save the information. Instead, you will receive an error message asking you to enter the missing information.

Text boxes with names appearing in regular type indicate that the requested information is non-mandatory and the additional information provided is useful to CTEP for the given subject area. These non-mandatory text boxes do not have to be completed to finalize the record. Information in some non-mandatory text boxes may actually be mandatory. This occurs when the information collected in this text box is mandatory only in certain circumstances. If this is the case, then when you choose **Save**, a message will appear identifying the text box that requires information.

When you position the insertion point in a text box, the type of information requested displays on the status bar at the bottom of the screen. After inserting the information into a text box, press **Enter**; the insertion point will then move to the next text box. If a text box is too small to show the entire value at once, then use the **Home** and **End** keys on the keyboard to view all of the contents.

Some text boxes need to be highlighted before any changes can be made. To highlight a text box, either click in the text box or use the up and down arrows on the keyboard to scroll the highlight to an adjoining row of text boxes.

LOV Command

Many text boxes contain a List of Values (LOV) command button. When you choose the LOV button, a dialog box similar to the one in Figure 6 will open to provide a list of items from which to select. If there are no values pertinent to the information currently shown on the screen, the LOV will not open.

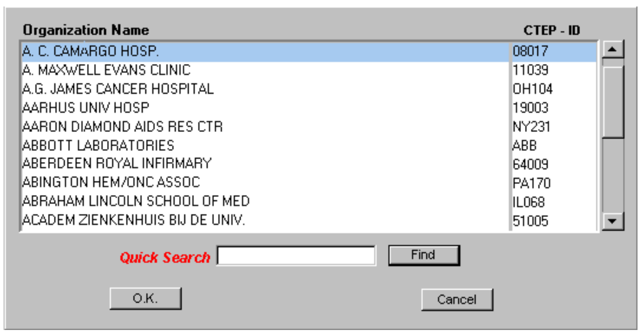


Figure 6 An LOV Dialog Box

If the list of items is large, you can use the scroll bar to view the entire list. Another method to search for the desired item is to enter a search criteria into the Quick Search text box and choose the **Find** command. This reduces the list of items to only those meeting the search criteria. In the **Find** text box the % symbol is a wild card character. PATS always conducts a search on the first field in the list.

When you select an item from a LOV and then click **OK**, the selected item is automatically inserted into the associated text box. You can also double-click the desired item to insert the item automatically and close the LOV at the same time. For all text boxes possessing an LOV, you may also type in the value. You must spell your entry to match the LOV value; otherwise, the entry will not be accepted.

Dates

Unless otherwise noted, enter dates in the format MM/DD/YYYY; that means Month/Day/Year, where month and day contain two digits, and year four digits. For example, enter January 4, 1999 as 01/04/1999.

Calendar Command

The **Calendar** command provides an easy and fast method to insert a date into an associated text box. When you choose the **Calendar** command button, the Calendar dialog box appears as shown in Figure 7.

Figure 7 Calendar Dialog Box

The dialog box appears with the current month shown. The currently selected date appears in blue. You can click a date to select it and then click **OK** to have the date placed into the associated text box. You can click the arrows at the top of the dialog box to change the month and the year. The left hand set of arrows controls the month, the right hand set controls the year.

Save

The **Save** commands on the **File** menu and the toolbar allow you to save information permanently. Use the **Save** command before exiting a screen, otherwise you may lose all the information you entered. If you have made changes and try to exit the screen without using **Save**, a message box appears asking if you want to save your changes. On the Document Abstraction screen, you will use the **Send** command. Once the save is complete, a “success” message appears on the status bar at the bottom of the screen.

CAUTION – When entering a new investigator registration, the investigator’s Last Name, First Name, Middle Name, and Suffix cannot be changed after the **Save** command is used. Before committing or saving data, check to see that the information is correct.

Exit and Close

The **Exit** and **Close** commands both have the same function of closing the dialog box or screen in which they are located. Note that the **Exit** or **Close** commands will not function if the **Enter Query** command is active. Ending a query by using the **Cancel Query** command will solve this problem.

Section 3 Document Evaluation

Enterprise Query Wizard Screen

Enterprise Query Wizard Screen

The Enterprise Query Wizard (EQW) performs a dual function. It allows you to

- search for protocols meeting specific criteria.
- determine whether a protocol already exists in the PATS database.

You can access the EQW through the PATS interface or through the separate EQW application on the CTEP Enterprise Front Panel. Refer to the Enterprise Query Wizard User's Guide for more detailed information.

The Enterprise Query Wizard screen (shown in

Figure 8) provides the platform from which to perform these tasks.

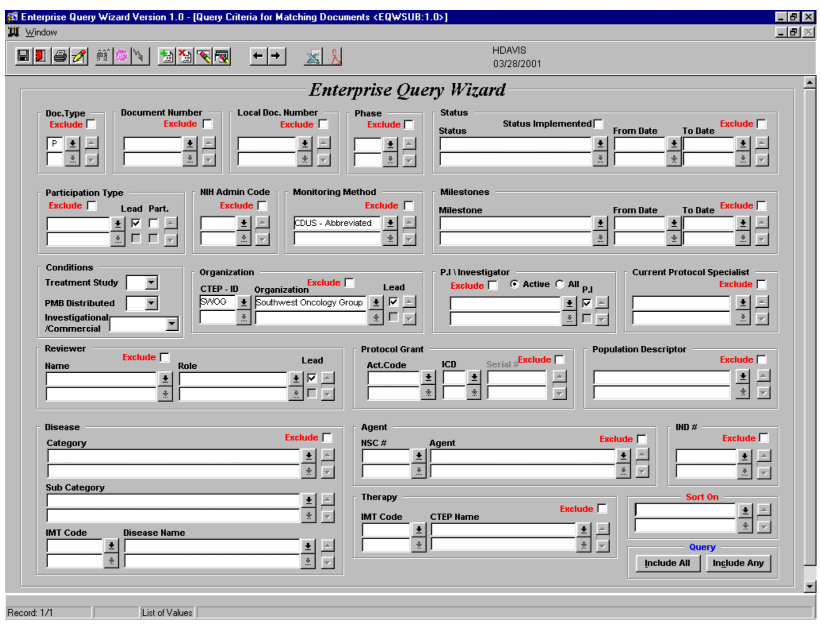
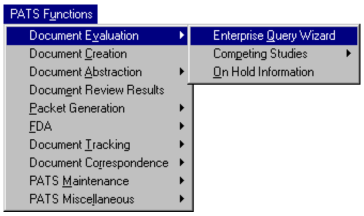


Figure 8 Enterprise Query Wizard Screen



Accessing the Enterprise Query Wizard Screen

1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Evaluation** to display the submenu.
3. Click **Enterprise Query Wizard**. The **Enterprise Query Wizard** screen appears.

Entering New Data in the Enterprise Query Wizard Screen

When you click the drop-down arrow button next to a field, a drop-down List of Values displays. Select the option you want to use from the list and click **OK**. You may also enter the value directly into the field.

1. Select or enter ‘P’ for Protocol in the Document Type field.
2. Continue selecting or entering document data in the fields you need to complete in order to conduct your search.

   Where you see two closely related fields within a group box, you will find that the system automatically enters data into the one field when you select or enter data into the other. You can select or enter data into either field.

   Where you see From and To Date fields (such as, Current Status or Milestone), you can narrow your query by specifying a date range for which that information is appropriate.

3. Locate the Sort On box at the lower right corner of the screen. Select the appropriate sorting filters in order to sort the documents in a specific manner.
4. Click on the **Include All** button under the Query, if you want to retrieve all documents meeting all the parameters you selected on this page. Click on the **Include Any** button to retrieve documents that meet any of the query criteria.

   Please note that if you have filled in all of the fields, it is still possible to filter out some of the information. If you do not want to include the values selected for certain fields in the query you are generating, click the **Exclude** check box above any field you do not want included in the query criteria. The remaining values (the ones you do not exclude) will be included in the query criteria. If the field is not populated, you do not need to click the **Exclude** check box.

   The documents meeting your query criteria display on the Query Results screen (shown in Figure 9)

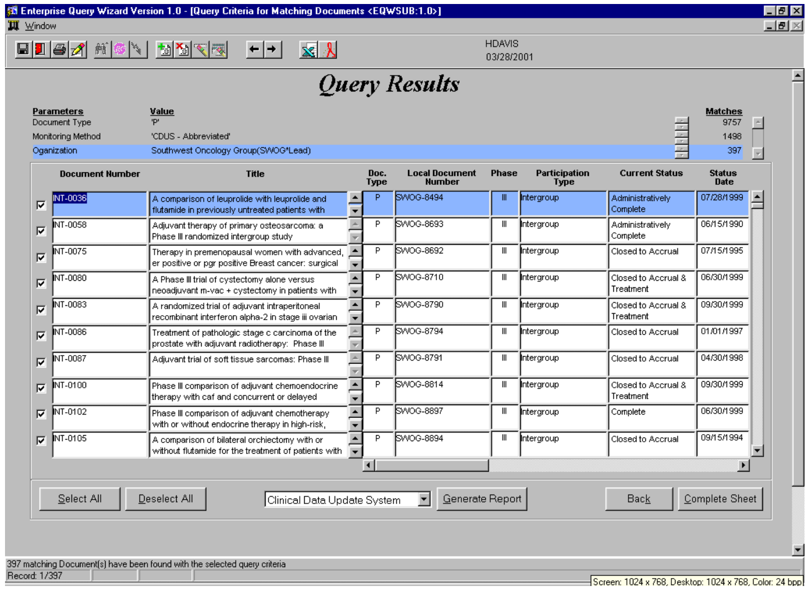


Figure 9 Query Results Screen

5. Review the results. You can select the documents you want to see in more detail

6. Click **Complete Sheet** to print out the data for the protocol that you have displayed on the Query Results screen.

   The Design Results screen (Figure 10) appears. You can now further narrow down the data you want to print. Select the check boxes for the data you want to show on the report. Select the **Complete Report** check box to print all the data for this protocol.

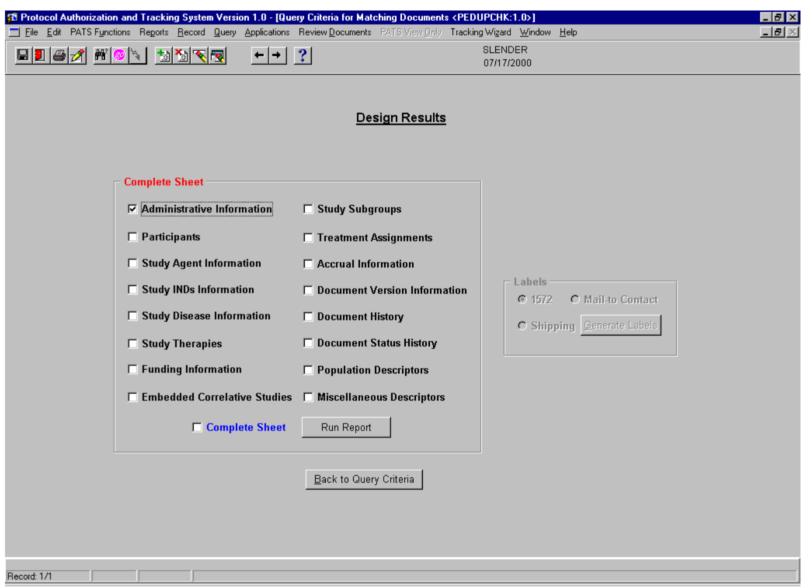


Figure 10 Design Reports Screen

   Select an option under Labels to generate a mailing label for this protocol.

7. Click **Run Report** to generate and print the report you want for this protocol.

Competing Studies

Query Criteria for Competing Studies – By Document Number Screen

Once you have determined whether the protocol already exists in the database, you may want to locate other protocols with similar criteria. This screen (shown in Figure 11) assists you to locate such protocols.

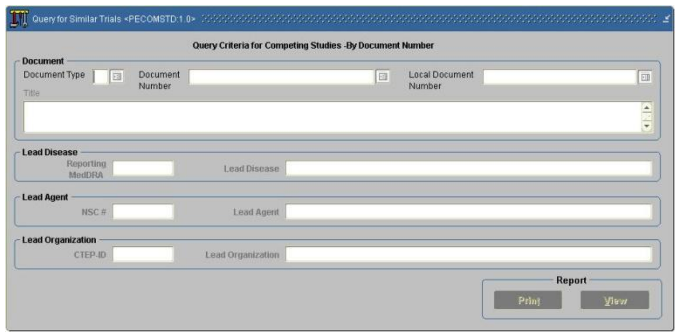
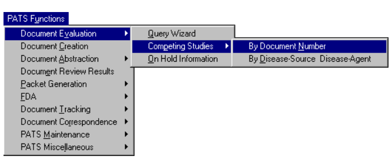


Figure 11 Query Criteria for Competing Studies – By Document Number Screen

Accessing the Query Criteria for Competing Studies – By Document Number Screen



1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Evaluatio**n to display the submenu.
3. Point to **Competing Studies**, and then click **By Document Number**. The Query Criteria for Competing Studies – By Document Number screen appears.

Entering New Data in the Competing Studies – By Document Number Screen

1. Click the **Enter Query** button from the toolbar or press **F7** on your keyboard.
2. Select or enter ‘P’ for Protocol in the Document Type field.
3. Select or enter the Document Number.
4. Click the **Execute Query** button on the toolbar to execute the query or press **F8** on your keyboard.

   Information for Lead Disease, Lead Agent, and Lead Organization fields will populate based on the information available in the system. A message stating the number of matches found displays on the status bar in the lower left corner of the screen.

5. Decide whether you want to view or print the report.

   To print the report, click the **Print** button.

   To view the report, click the **View** button. You may print the report from the View screen, once you have reviewed the report.

Query Criteria for Competing Studies – By Disease-Source & Disease-Agent Screen

The purpose of this screen (shown in Figure 12) is to help you determine if there are other studies with criteria similar to the protocol you want to add to PATS. With this screen you may use the disease source and leading disease agent as the basis for your search criteria.

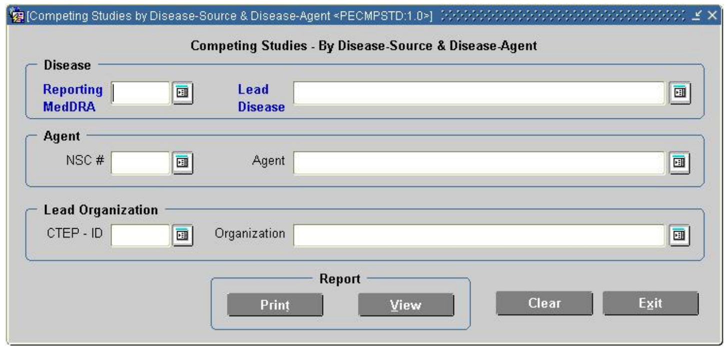
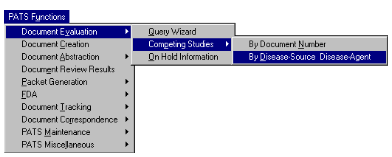


Figure 12 Query Criteria for Competing Studies – By Disease-Source & Disease-Agent Screen

Accessing the Query Criteria for Competing Studies – By Disease-Source & Disease-Agent Screen



1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Evaluatio**n to display the submenu.
3. Point to **Competing Studies,** then **By Disease-Source & Disease-Agent**. The Query Criteria for Competing Studies – By Disease-Source & Disease-Agent screen appears.

Entering New Data in the Competing Studies – By Disease-Source & Disease-Agent Screen

1. Select the appropriate code or disease name for either the IMT Code field or the Disease field under Disease. Whichever field you choose to populate first will cause the other field to populate.
2. Select the appropriate number or agent name for either NSC# field or the Agent field under Agent. Whichever field you choose to populate first will cause the other field to populate.
3. Select the appropriate entry for the either the CTEP-ID field or the Organization field under Lead Organization. Whichever field you choose to populate first will cause the other field to populate.
4. Decide whether to view the report or send it immediately to the printer.

   To print the report, click the **Print** button.

   To view the report, click the **View** button. You may print the report from the View screen, once you have reviewed the report.

   To exit the screen, click the **Exit** button.

On Hold Information

Document On-Hold Information Screen

The purpose of this screen (shown in Figure 13) is to put a document on hold if it has not met specific criteria for processing.

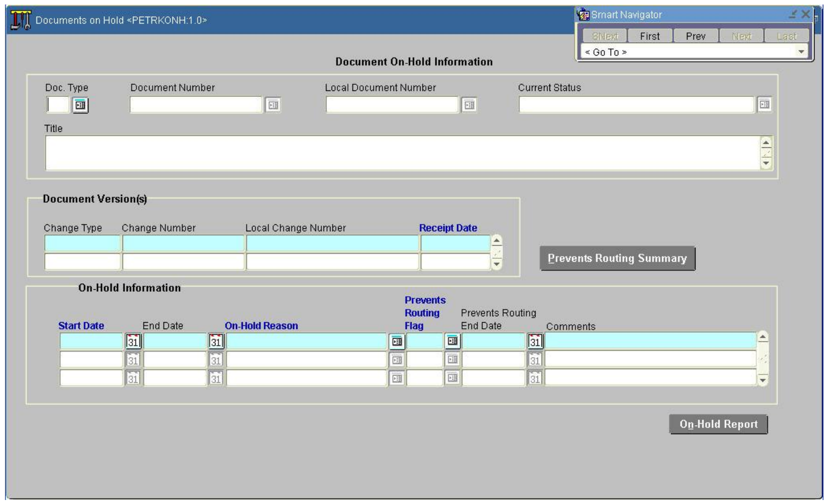
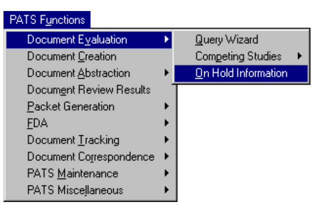


Figure 13 Document On-Hold Information Screen

Accessing the Document On-Hold Information Screen



1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Evaluation** to display the submenu.
3. Click **On Hold Information**. The Document On-Hold Information screen appears.

Entering New Data in the Document On-Hold Information Screen

Depending on when you access the Document On-Hold Information screen, the Document Type, Document Number, Local Document Number, Current Status, and Title fields may or may not be populated.

If you access this screen before creating a document, and you want to pull up a document to place on hold, the general document information will not be populated. You will query the database to locate the document to place on hold.

If you have been working with a document and are at the Document Review stage, for example, and need to place that document on hold, then the fields will be populated when you access this screen.

1. Follow these steps to query the database if you need to do so. Otherwise, go to Step 2.

   Click **Enter Query** on the toolbar.

Enter the Document Type and Document Number.

Click **Execute Query** on the toolbar. The Local Document Number, Current Status, and Title fields populate.

2. Enter or select the Start Date and End Date for the on-hold time period.
3. Select the On-Hold Reason.
4. Enter any comments you want to record.
5. Click the **Save** icon on the toolbar to save the information on the screen.

   A message appears on the status bar stating:

   Transaction complete: # records applied and saved.
6. If you want a report of this information, click the **On-Hold Report** button. If not, click the **Exit** icon on the tool bar to exit screen.

Section 4 Document Creation

Document Creation

Document Creation Screen

This purpose of this screen (shown in Figure 14) is to abstract the primary administrative data elements into the database.

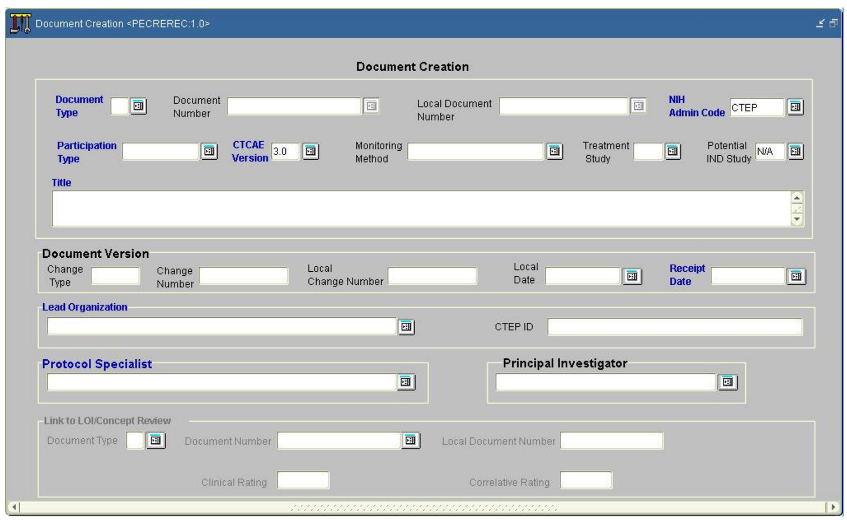
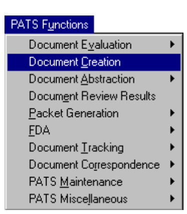


Figure 14 Document Creation Screen



Accessing the Document Creation Screen

1. From the Main menu, open the **PATS Functions** menu.
2. Click **Document Creation**. The Document Creation screen appears.

Entering New Data in the Document Creation Screen

When you click the drop-down arrow button next to a field, a drop-down List of Values displays. Select the option you want to use from the list and click **OK**. You may also enter the value directly into the field.

1. Select or enter ‘P’ for Protocol in the Document Type field.

2. Continue selecting or entering document data.

   Where you see two closely related fields within a group box, you will find that the system automatically enters data into the one field when you select or enter data into the other. You can select or enter data into either field.

   Please note that the Lead Organization List of Values is dependent upon the Participation Type you select. If, for example, you select Cancer Center in the Participation Type field, then only Cancer Centers and Single Institutions will appear in the Lead Organization List of Values. The CTEP-ID field will populate based on the Lead Organization you select.

   If the investigator status is other than Active, the system automatically sends PMB an e-mail message requesting the necessary steps to activate the Principal Investigator.

   The Principal Investigator List of Values depends on the Lead Organization selected. Only Principal Investigators affiliated with the Lead Organization will appear. Should you need additional assistance, consult the Address Maintenance Module User's Guide.

3. Select the Protocol Specialist from the drop down list. By default, the system will enter your name automatically if you are a Protocol Specialist.

4. Select LOI or Concept Review in the Link for the LOI/Concept Review field. Select the Document Number. If the Local Document Number is in the system, it will populate based on the information entered in the previous field.

   Please note that you can only link a protocol to a LOI or Concept Review that has already been abstracted and approved in the system.

5. Click the **Save** icon on the toolbar to save the information on the screen.

   A message appears on the status bar stating:

   Transaction complete: # records applied and saved.

   The information abstracted in this screen may be used in several other screens.

   At this point, the system automatically creates a folder with the Protocol Number on the network. This folder contains five sub-folders.

Ingoing	Stores all incoming correspondence
Outgoing	Stores all outgoing correspondence
Document	Stores all documents relating to the protocol, such as, the original protocol and any subsequent revisions and amendments
Review	Stores all reviewer comments
Consensus	Stores all consensus reviews

6. Exit screen through the **Exit** icon on the toolbar.

Section 5 Document Abstraction

General Information

General Information – Protocol Screen

The purpose of this screen (Shown in Figure 15) is to abstract the general information data elements, namely study types, rationale, objectives, and eligibility criteria.

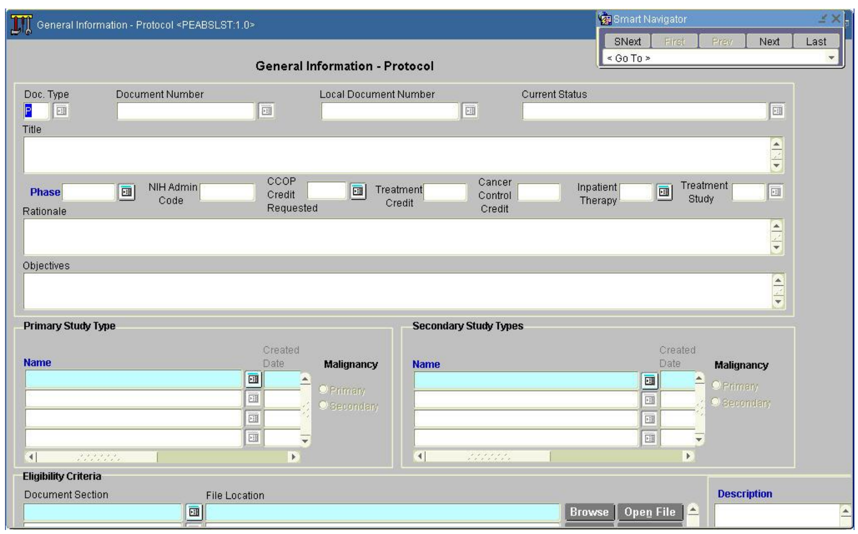
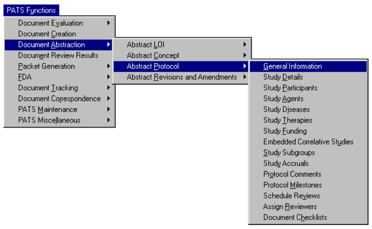


Figure 15 General Information – Protocol Screen

The Smart Navigator feature on the Document Abstraction screens provides two functions to speed up your work.

- When you are ready to save your entries you can click the **Save** button on the toolbar, or you can click the **Next** button in the Smart Navigator. The **Save** command saves your work. You can then select the next screen. The **Next** button saves your entries and moves you automatically to the next Document Abstraction screen.
- When you are working with a Document Abstraction screen and want to skip to another screen, not necessarily the next one in sequence, you can select the screen you want use to from the Go To list in the Smart Navigator. You can also use the **First**, **Previous**, **Next**, and **Last** buttons to navigate among the screens.



Accessing the General Information – Protocol Screen

1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Abstraction** to display the submenu.
3. Point to **Abstract Protocol**, and then click **General Information**. The General Information – Protocol screen appears.

Entering New Data in the General Information – Protocol Screen

1. The Document Type, Document Number, Local Document Number, Current Status, and Title text fields pre-populate based on the information already entered.
2. Select or enter information in the Phase, NIH Admin Code, CCOP Credit Requested, Treatment Credit, Cancer Control Credit, and Inpatient Therapy fields.
3. Select the appropriate study in the Treatment Study field

   It is important to complete the Treatment Study field before moving to Study Types. If you select No from the List of Values, the following message appears:

   Non-treatment studies must have study types. Do you want to proceed?

   Choose **Yes**.

   If you choose Yes for Treatment Study, you move to Study Types.
4. Select the appropriate information in the Study Types field.
5. Type Rationale in the text field provided. To edit the document in this field, go to the **Edit** menu and select **Edit**. The Edit dialog box appears for you to type the information and make changes as necessary.
6. Enter the protocol's Objectives in the text field provided. To edit the document in this field, go to the **Edit** menu and select **Edit**. The Edit dialog box appears for you to type the information and make changes as necessary.
7. Select the appropriate information in the Document Section field.
8. If a file exists relating to this information, click the **Browse** button and navigate to that file's location. Select the file to populate the File Location field.
9. Click in the Description field and type the information that describes the eligibility criteria.
10. Click the **Save** icon on the toolbar to save the information on the screen.

    A message appears on the status bar stating:

    Transaction complete: # records applied and saved.

    The information abstracted in this screen may be used in several other screens.

Study Details

Study Details Abstracted at PIO Screen

The purpose of this screen (shown in Figure 16) is to abstract the administrative details and descriptors for the protocol.

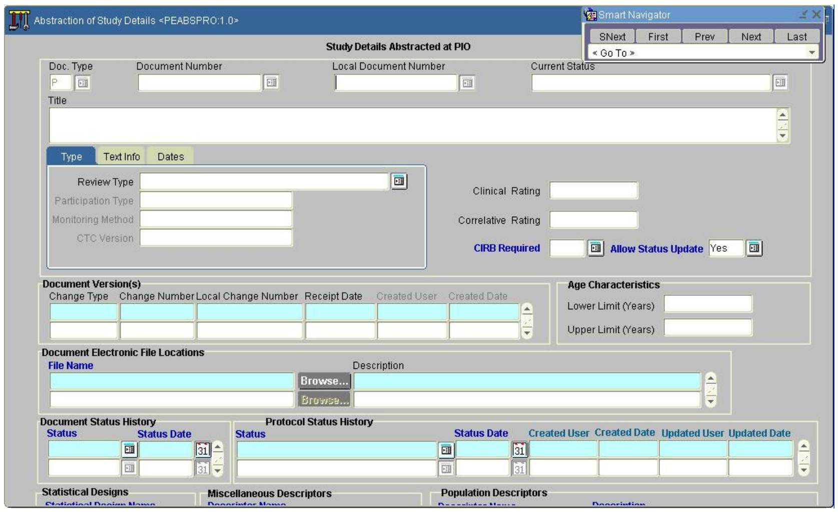
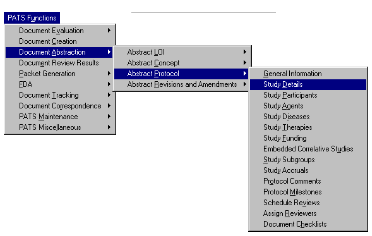


Figure 16 Study Details Abstracted at PIO Screen



Accessing the Study Details Abstracted at PIO Screen

1. From to the Main menu, click the **PATS Functions** menu.
2. Point to **Document Abstraction** to display the submenu.
3. Point to **Abstract Protocol,** and then click **Study Details**. The Study Details Abstracted at PIO – Protocol screen appears.

Entering New Data in the Study Details Abstracted at PIO Screen

The Document Type, Document Number, Local Document Number, Current Status, and Title text fields pre-populate based on the information already entered.

1. Enter the name of the file in File Name text field under the Document Electronic File Location heading. You may also select the file name by using the **Browse** button and locating the file.
2. Select the appropriate response for the Status field under Document Status History. Enter the Status Date or select the Status Date from the calendar.

   The Protocol Status History fields and the Current Status field automatically populate. You cannot update these fields once you have entered the information. Only system administrators at CTIS can make changes to these fields.
3. Select the appropriate name in the Statistical Design Name field under Statistical Designs.

4. Select the appropriate name in the Descriptor Name field under Miscellaneous Descriptors.
5. Select the appropriate name in the Descriptor Name field under Population Descriptors. The Descriptor Name and Description populate.
6. Click the **Save** icon on the toolbar to save the information on the screen

   A message appears on the status bar stating:

   Transaction complete: # records applied and saved.

   The information abstracted in this screen may be used in several other screens.
7. Click **Exit** icon on toolbar to exit screen.

Study Participants

Study Participants – Protocol Screen

The purpose of this screen (shown in Figure 17) is to abstract participating organizations on the protocol and their corresponding investigators.

Letters of Intent and Concept Reviews do not abstract this information.

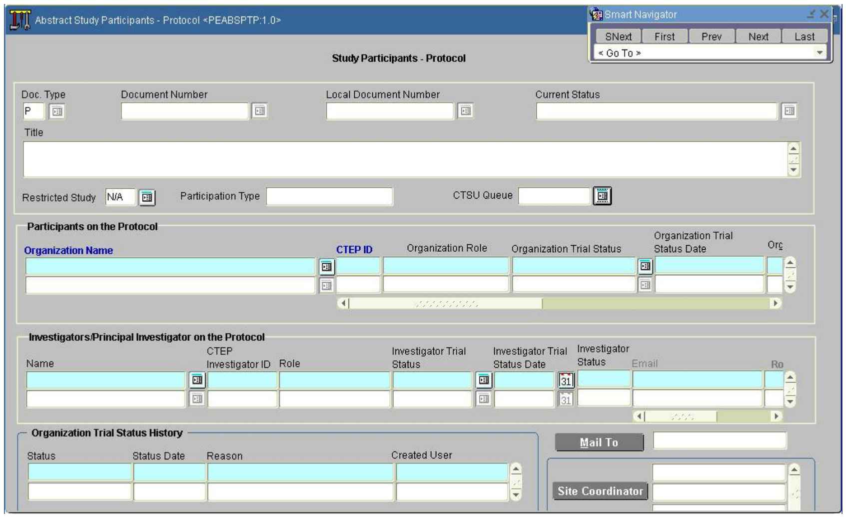
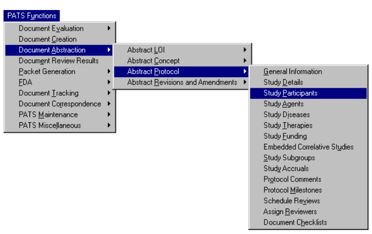


Figure 17 Study Participants – Protocol Screen

Accessing the Study Participants – Protocol Screen



1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Abstraction** to display the submenu.
3. Point to **Abstract Protocol**, and then click **Study Participants**. The Study Participants - Protocol screen appears.

Entering New Data in the Study Participants – Protocol Screen

1. The Document Type, Document Number, Local Document Number, Current Status, Title, Restricted Study, and Investigator Specific text fields automatically populate from information already entered in the database.
2. Select the appropriate name in the Organization Name field under Participants on the Protocol. Once you have chosen the Organization Name, the CTEP ID and Organization Role fields also populate**.**

   Please note that the Organization Name List of Values is dependent on the Participation Type you entered in the Document Creation screen. If, for example, Cancer Center is selected as the Participation Type, only Cancer Centers and Single Institutions will populate the List of Values.

   If the Participation Type of the protocol is Group or Intergroup, it is possible for institutions outside of their rosters to participate on the protocol. If you click the drop down arrow button and the institution that you are looking for is unavailable, click the **Outside Roster** button and check the List of Values.

3. Scroll to the right and click on the drop down arrow button next to Organization Trial Status in the Participants on the Protocol region to populate the text box from the List of Values.
4. Click the drop-down arrow button next to Organization Trial Status Date text box under Participants on the Protocol to populate the text box with the date from the Calendar.
5. Type in the Local Document Number in the designated text box under Participants on the Protocol.
6. Type in the Comments in the designated text box under Participants on the Protocol.
7. Select the appropriate name in the Name field under Investigator on the Protocol. The Role field populates when you select the Investigator Name.

   Please note that the only investigators to appear on the list are those entered into the system and associated with the organization you have selected.
8. Select the appropriate status and date in the Investigator Trial Status Date fields in the Investigator/Protocol Chair on the Protocol region.
9. To abstract the postal information, click the **Mail To** button and follow instructions on page 28.
10. Click the **Save** icon on the toolbar to save the information on the screen.

    A message appears on the status bar stating:

    Transaction complete: # records applied and saved.
11. Click the **Exit** icon on the toolbar to exit screen.

Study Participants – Mail-to Contact Information

Mail-to Contact Information Screen

The purpose of this screen (shown in Figure 18) is to abstract all the postal information necessary for contacting the investigator(s) or contact(s).

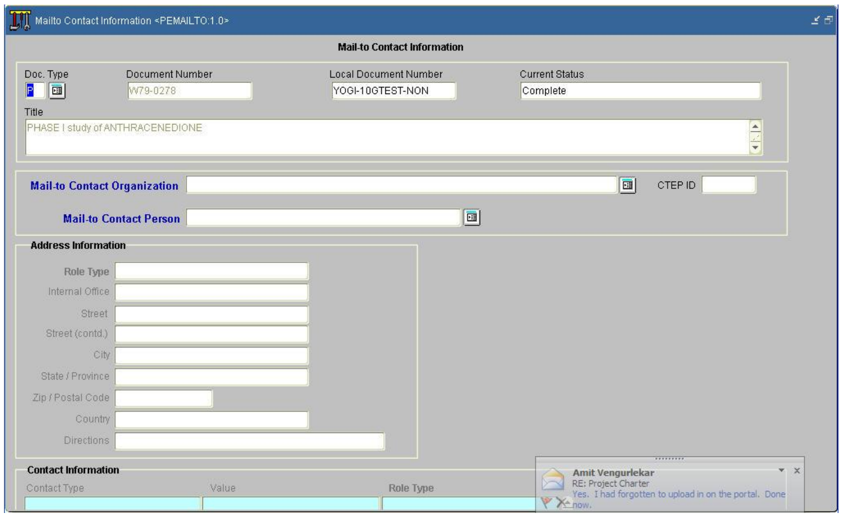


Figure 18 Study Participants: Mail-To Contact Information Screen

Accessing the Mail-to Contact Information Screen

1. From the Study Participants – Protocol screen, click the **Mail To** button. The Mail-To Contact Information screen appears.

Entering New Data in the Mail-to Contact Information Screen

1. The Document Type, Document Number, Local Document Number, Current Status, and Title fields all populate based on information from the previous screen.
2. Select the appropriate organization and contact person for the Mail-to Contact Organization text boxes.

   The options available on these lists are restricted to the lead and participating organizations on the study.

   The Address Information and Contact Information regions automatically populate.

   Please note that the Organization and Contact Person fields will populate correctly only if the addresses reside in the Address Maintenance Module. If you need additional assistance, please consult the Address Maintenance Module User's Guide.
3. Click the **Save** icon on the toolbar to save the information on the screen.

   A message appears on the status bar stating:

   Transaction complete: # records applied and saved.
4. Click the **Exit** icon to return to the Study Participants – Protocol screen.

Study Agents

Study Agents and INDs – Protocol Screen

The purpose of this screen (shown in Figure 19) is to abstract the agent(s) and IND(s) information that is being studied on the protocol.

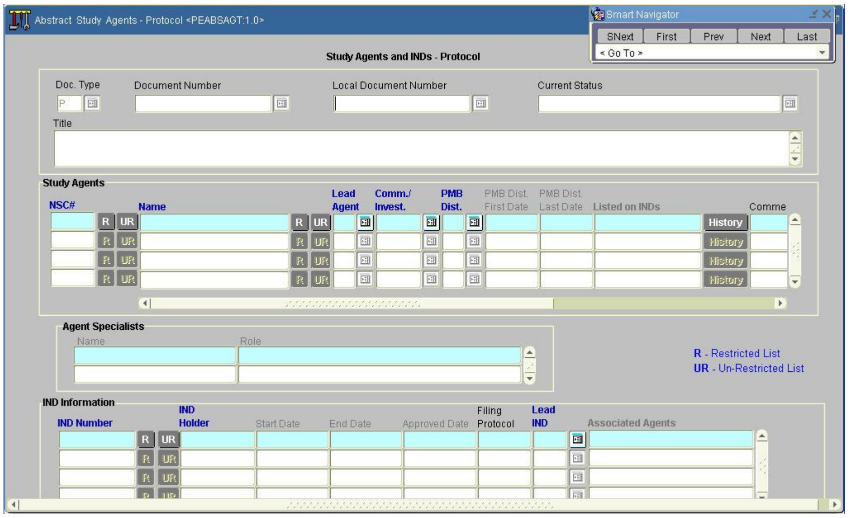
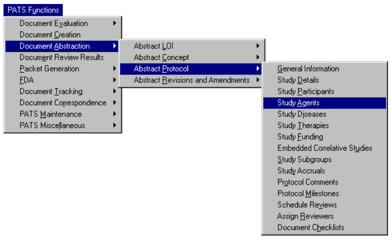


Figure 19 Study Agents and INDs – Protocol Screen

Accessing the Study Agents and INDs – Protocol Screen



1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Abstraction** to display the submenu.
3. Point to **Abstract Protocol**, and then click **Study Agents**. The Study Agents screen appears.

Entering New Data in the Study Agents and INDs – Protocol Screen

The Document Type, Document Number, Local Document Number, Current Status, and Title text fields pre-populate based on the information already entered.

1. Select the appropriate NSC Number and Agent Name for the NSC Number and Name fields. You can select just the Name; the system enters the NSC Number automatically.
2. Select the appropriate entries for Lead Agent, Commercial/Investigational, CTEP Supplied.
3. Enter any additional information for this Protocol in the Comments field.
4. Select the appropriate value for IND Number under IND Information. The IND Number, IND Holder, Start Date, End Date, and Approved Date fields automatically populate as appropriate.
5. Select the appropriate response for IND Filing Flag.

6. Select the appropriate response for Lead IND Flag.
7. Click the **Save** icon on the toolbar to save the information in this screen. The Agent Specialists' Name and Role fields automatically populate, if they are associated in the Enterprise Maintenance System (EMS).

   A message appears on the status bar stating:

   Transaction complete: # records applied and saved.

Study Diseases

Study Diseases - Protocol Screen

The purpose of this screen (shown in Figure 20) is to abstract the diseases that are being studied on the protocol.

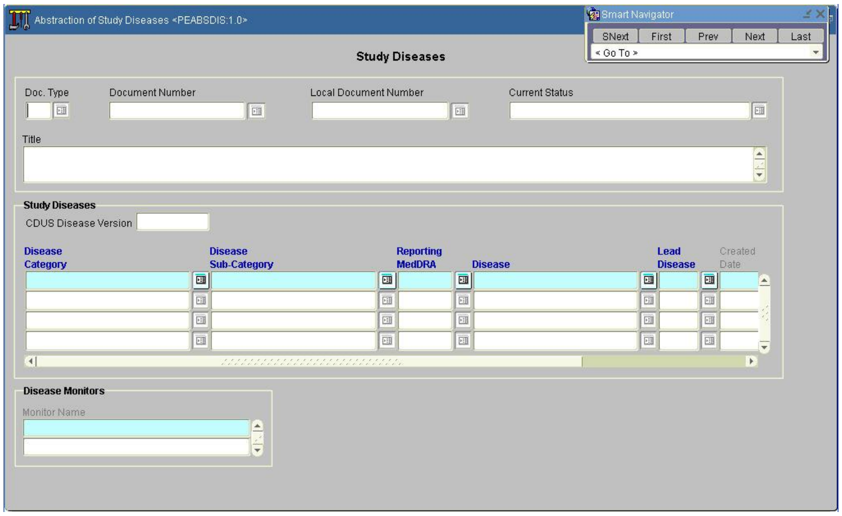
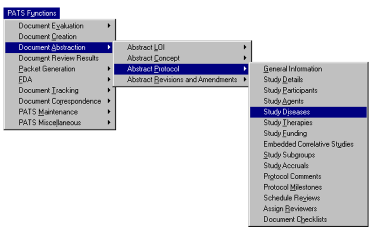


Figure 20 Study Diseases – Protocol Screen



Accessing the Study Diseases – Protocol Screen

1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Abstraction** to display the submenu.
3. Point to **Abstract Protocol**, and then click **Study Diseases**. The Study Diseases - Protocol screen appears.

Entering New Data in the Study Diseases – Protocol Screen

The Document Type, Document Number, Local Document Number, Current Status, and Title text fields pre-populate based on the information already entered.

1. Select the appropriate entries for Disease Category and Disease Sub-Category.
2. Select the appropriate entries for the IMT Code, CTEP Name, and Lead Disease.

   The Disease Monitors field automatically populates.
3. Click the **Save** icon on the toolbar to save the information on the screen.

   A message appears on the status bar stating:

   Transaction complete: # records applied and saved.

Study Therapies

Letters of Intent and Concept Reviews do not abstract this information.

Study Therapies – Protocol Screen

The purpose of this screen (shown in Figure 21) is to abstract the therapies on the study.

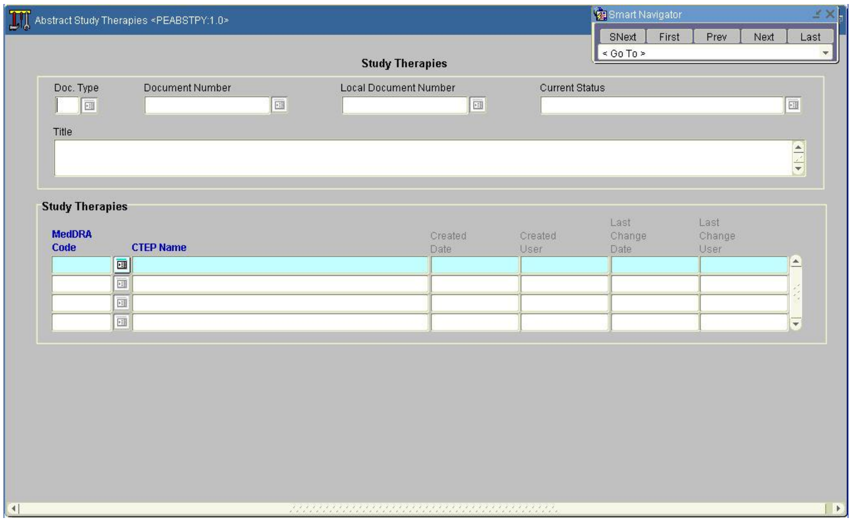
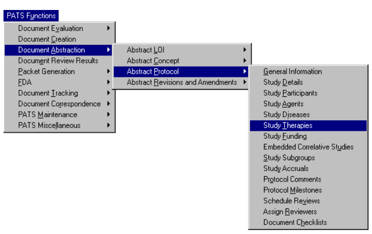


Figure 21 Study Therapies – Protocol Screen



Accessing the Study Therapies – Protocol Screen

1. From the Main menu, open on the **PATS Functions** menu.
2. Point to **Document Abstraction** to display the submenu.
3. Point to **Abstract Protocol**, and then click **Study Therapies**. The Study Therapies - Protocol screen appears.

Entering New Data in the Study Therapies – Protocol Screen

The Document Type, Document Number, Local Document Number, Current Status, and Title text fields pre-populate based on the information already entered.

1. Select the appropriate entries for the IMT Code and CTEP Name.
2. Click the **Save** icon on the toolbar to save the information on the screen.

   A message appears on the status bar stating:

   Transaction complete: # records applied and saved.

Study Funding

Study Funding – Protocol Screen

The purpose of this screen (shown in Figure 22) is to abstract the funding details of the study.

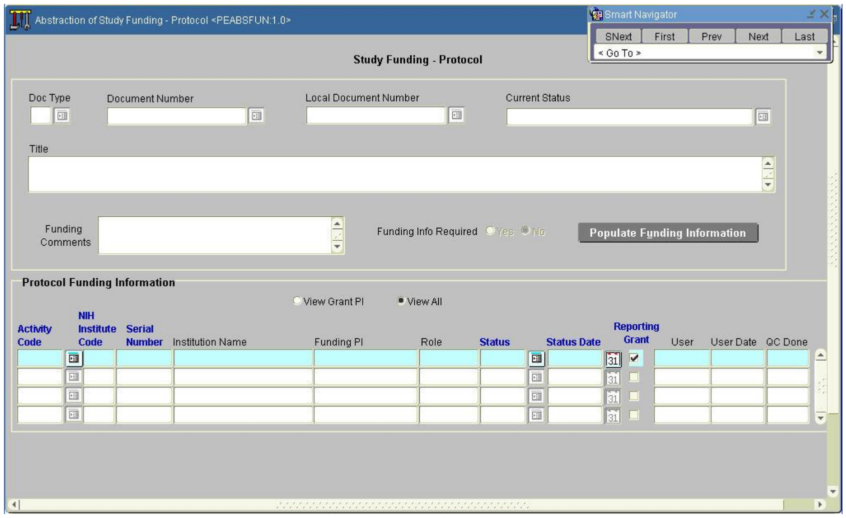
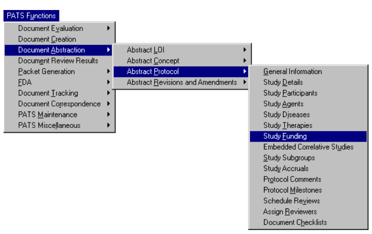


Figure 22 Study Funding – Protocol Screen

Accessing the Study Funding – Protocol Screen



1. From the Main Menu, open the **PATS Functions** menu.
2. Point to **Document Abstraction** to display the submenu.
3. Point to **Abstract Protocol**, and then click **Study Funding**. The Study Funding - Protocol screen appears.

Entering New Data in the Study Funding – Protocol Screen

The Document Type, Document Number, Local Document Number, Current Status, and Title text fields pre-populate based on the information already entered.

1. Select the appropriate entry for ICD. The Serial Number and Activity Code fields populate automatically.
2. Select the appropriate name for the grant's Principal Investigator. The Organization Name field populates automatically.
3. Click the **Save** icon on the toolbar to save the information on the screen.

   A message appears on the status bar stating:

   Transaction complete: # records applied and saved.

Embedded Correlative Studies

Embedded Correlative Studies – Protocol Screen

The purpose of this screen (shown in Figure 23) is to abstract the Embedded Correlative Studies, Correlative Study Classifications, correlative grants, and study tissue banks.

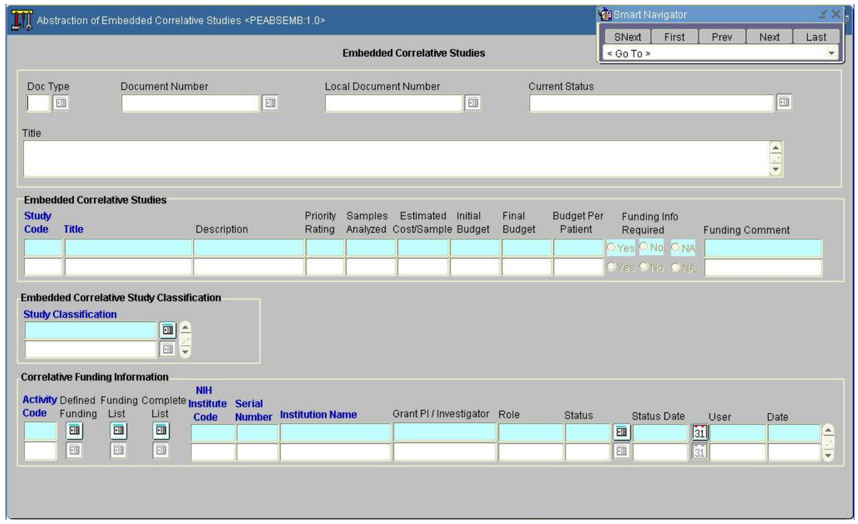
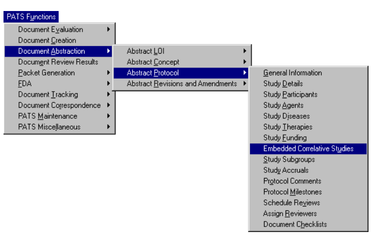


Figure 23 Embedded Correlative Studies – Protocol Screen

Accessing the Embedded Correlative Studies – Protocol Screen



1. From the Main Menu, open the **PATS Functions** menu.
2. Point to **Document Abstraction** to display the submenu.
3. Point to **Abstract Protocol**, and then click **Embedded Correlative Studies**. The Embedded Correlative Studies - Protocol screen appears.

Entering New Data in the Embedded Correlative Studies – Protocol Screen

The Document Type, Document Number, Local Document Number, Current Status, and Title text fields pre-populate based on the information already entered.

1. Type the unique Study Code under Embedded Correlative Studies.
2. Type the Title in the Embedded Correlative Studies section in the text field provided.
3. Select the appropriate entry for the Study Classification field in the Embedded Correlative Study Classification region.
4. Select the appropriate entry for the ICD. The ICD, Serial Number and Activity Code fields populate.

5. Select the appropriate entry for the Organization Name field in the Correlative Grant Information. The Organization Name, CTEP ID and Grant P.I. Name fields populate.
6. Select the appropriate entry for the Organization Name field in the Study Tissue Banks. The Organization Name and CTEP ID fields populate.
7. Click the **Save** icon on the toolbar to save the information on the screen.

   A message appears on the status bar stating:

   Transaction complete: # records applied and saved.

Study Subgroups

Study Subgroups – Protocol Screen

Letters of Intent and Concept Reviews do not abstract this information.

The purpose of this screen (shown in Figure 24) is to abstract the subgroup details of the protocol. These details include subgroup definitions, therapies, and diseases.

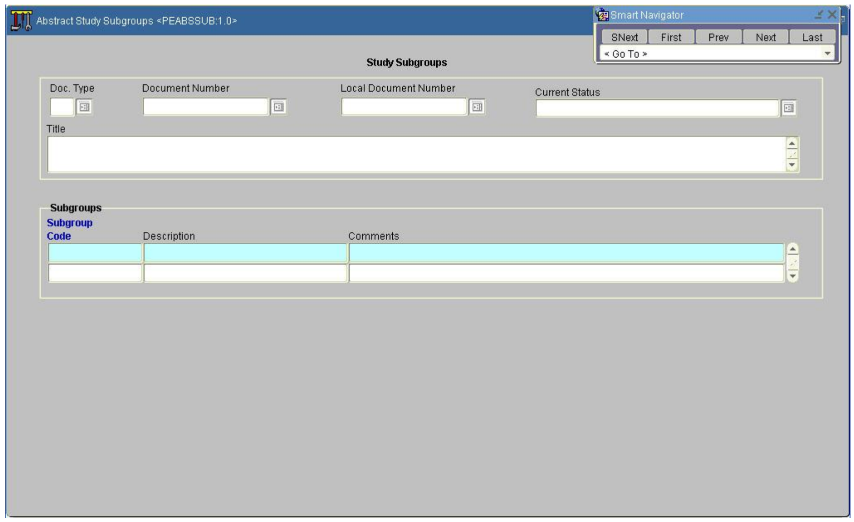
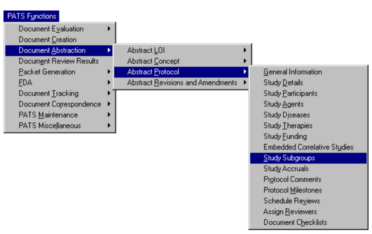


Figure 24 Study Subgroups – Protocol Screen

Accessing the Study Subgroups – Protocol Screen



1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Abstraction** to display the submenu.
3. Point to **Abstract Protocol**, and then click **Study Subgroups**. The Study Subgroups - Protocol screen appears.

Entering New Data in the Study Subgroups – Protocol Screen

The Document Type, Document Number, Local Document Number, Current Status, and Title text fields pre-populate based on the information already entered.

1. Type the Subgroup Code, Description and Comments in the appropriate text fields under the Subgroups heading.
2. Select the appropriate entry for the Category field
3. Type the Low Value and High Value in the designated text boxes.
4. Select the appropriate entry for the IMT Code field. The IMT Code and CTEP Name text fields populate.
5. Select the appropriate entry for the IMT Code field in the Subgroup Diseases section. The IMT Code and CTEP Name text fields populate.
6. Click the **Save** icon on the toolbar to save the information on the screen.

   A message appears on the status bar stating:

   Transaction complete: # records applied and saved.

Study Accruals

Study Accruals – Protocol Screen

The purpose of this screen (shown in Figure 25) is to abstract accrual details for the study.

Letters of Intent and Concept Reviews do not abstract this information.

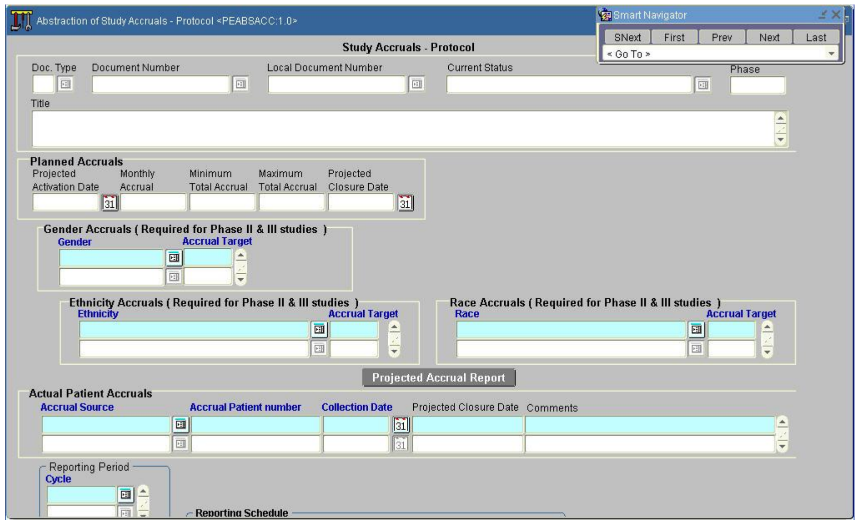
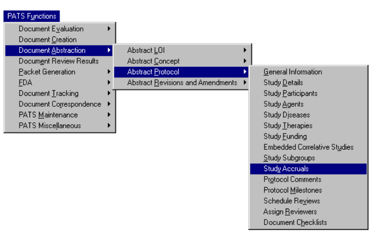


Figure 25 Study Accruals – Protocol Screen



Accessing the Study Accruals – Protocol Screen

1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Abstraction** to display the submenu.
3. Point to **Abstract Protocol**, and then click **Study Accruals**. The Study Accruals - Protocol screen appears.

Entering New Data in the Study Accruals – Protocol Screen

The Document Type, Document Number, Local Document Number, Current Status, Phase, and Title text fields pre-populate based on the information already entered.

1. Select the appropriate date from the calendar for the Projected Activation Date field in the Planned Accruals section.
2. Calculate the Monthly Accrual and enter the information in the Monthly Accrual field.
3. Enter the Minimum Total Accrual and Maximum Total Accrual in the proper fields.
4. The Projected Closure Date text box will automatically populate.

   You have the option of changing the Projected Closure Date from the calendar.

   Complete the following steps if the Protocol is a Phase III study only.

5. Select the appropriate entry for the Gender and Accrual Target in the Gender Accruals (Required for Phase III studies only) section.
6. Select the appropriate entry for Race and Accrual Target in the Race Accruals (Required for Phase III studies only) section.
7. Click the text field under Accrual Target in the Race Accruals (Required for Phase III studies only) section and select the appropriate response.
8. Select the appropriate Cycle under Reporting Period.
9. Enter the Reporting Range and select the Due Date under Reporting Schedule.
10. Click the **Save** icon on the toolbar to save the information on the screen.

    A message appears on the status bar stating:

    Transaction complete: # records applied and saved.

Protocol Comments

Protocol Comments Screen

The purpose of this screen (shown in Figure 26) is to abstract the comments on the document.

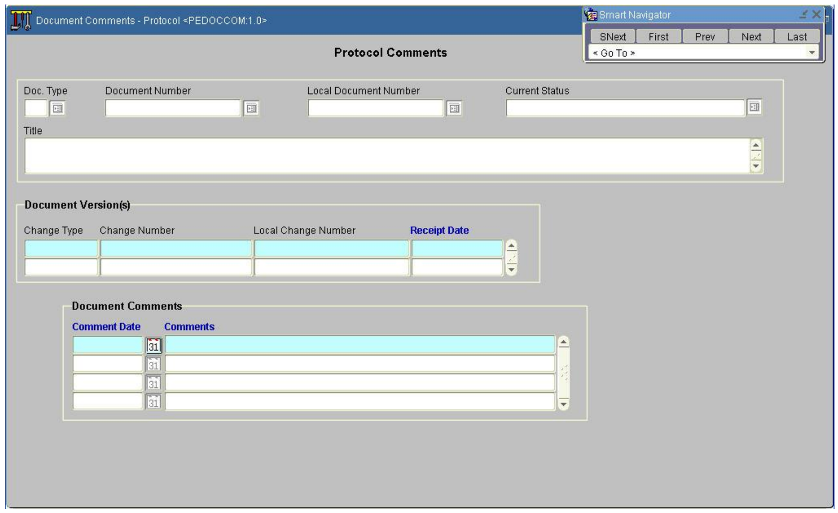
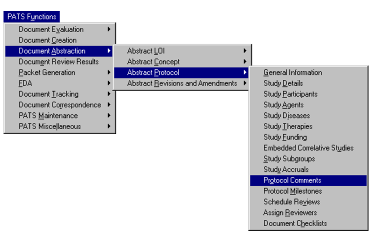


Figure 26 ***Protocol*** *Comments Screen*

Accessing the Protocol Comments Screen



1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Abstraction** to display the submenu.
3. Point to **Abstract Protocol**, and then click **Protocol Comments**. The Protocol Comments screen appears.

Entering New Data in the Protocol Comments Screen

The Document Type, Document Number, Local Document Number, Current Status, and Title text fields pre-populate based on the information already entered.

1. Select the appropriate date from the calendar for the Comment Date.
2. Type any comments in the Comment text field.
3. Click the **Save** icon on the toolbar to save the information on the screen.

   A message appears on the status bar stating:

   Transaction complete: # records applied and saved.

Protocol Milestones

Protocol Milestones Screen

The purpose of this screen (shown in Figure 27) is both to view and to insert the various milestones in the life cycle of the protocol.

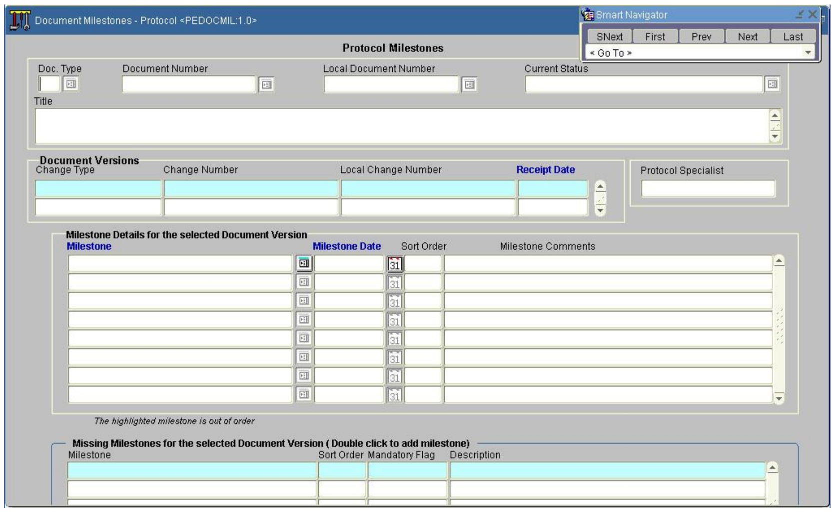
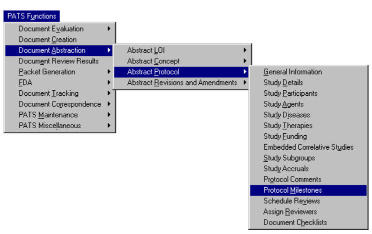


Figure 27 Protocol Milestones Screen

Accessing the Protocol Milestones Screen



1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Abstraction** to display the submenu.
3. Point to **Abstract Protocol**, and then click **Protocol Milestones**. The Protocol Milestones screen appears.

Entering New Data in the Protocol Milestones Screen

The Document Type, Document Number, Local Document Number, Current Status, and Title text fields pre-populate based on the information already entered.

1. Select the appropriate entry for the **Milestone** field in the Milestone Details section.
2. Select the appropriate date from the calendar for the **Milestone**.
3. Type in comments in the Milestone Comments text box as appropriate.
4. Click the **Save** icon on the toolbar to save the information on the screen.

   A message appears on the status bar stating:

   Transaction complete: # records applied and saved.

Schedule Reviews

Schedule Reviews Screen

The purpose of this screen (shown in Figure 28) is to schedule documents for review.

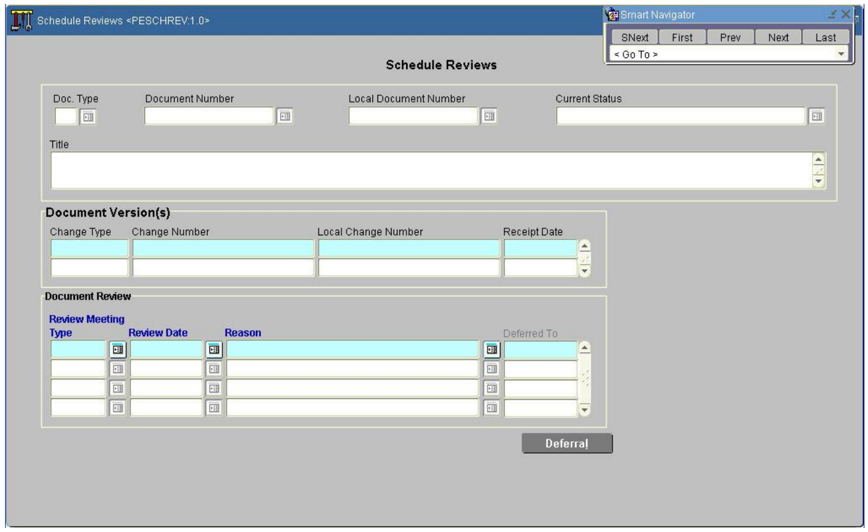
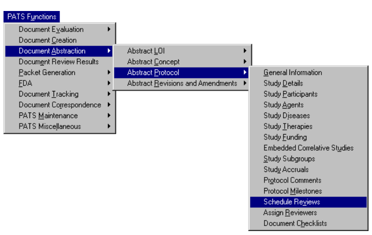


Figure 28 Schedule Reviews Screen



Accessing the Schedule Reviews Screen

1. From to the Main menu, open the **PATS Functions** menu.
2. Point to **Document Abstraction** to display the submenu.
3. Point to **Abstract Protocol**, and then click **Schedule Reviews**. The Schedule Reviews screen appears.

Entering New Data in the Schedule Reviews Screen

The Document Type, Document Number, Local Document Number, Current Status, and Title text fields pre-populate based on the information already entered.

1. Select the entries for the Document Type, Document Number, and Current Status fields.
2. Click the **Execute Query** button from the toolbar. The Document Version(s) and Document Review regions pre-populate.
3. Select the appropriate entries Review Meeting Type, Review Meeting Date, and Reason.
4. Click the **Save** icon on the toolbar to save the information on the screen. You have the option to change the review dates prior to completing this step.

   A message appears on the status bar stating:

   Transaction complete: # records applied and saved.
5. Use the **Deferral** button to reschedule review dates.

   The Document Review Results screen appears and you can adjust the review schedule.

Assign Reviewers

Assign Reviewers Screen

The purpose of this screen (shown in Figure 29) is to assign reviewers for various kinds of reviews.

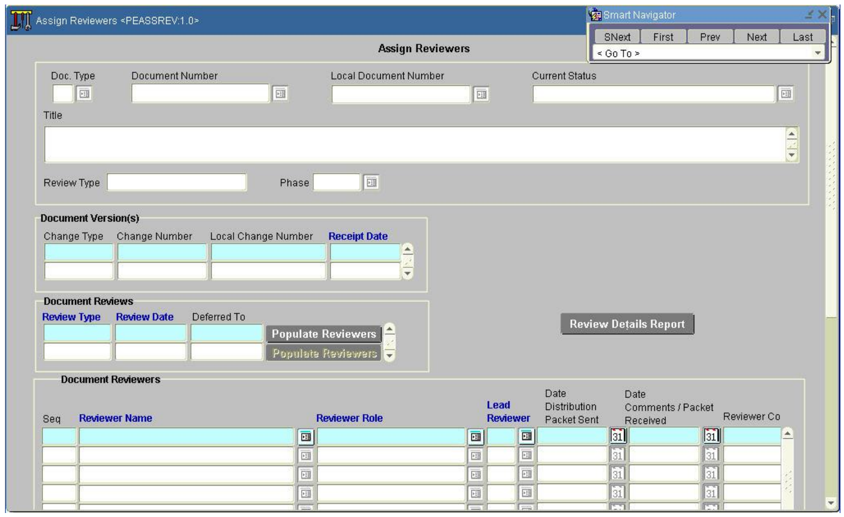
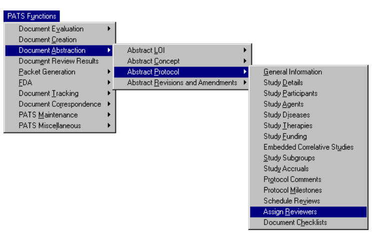


Figure 29 Assign Reviewers Screen



Accessing the Assign Reviewers Screen

1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Abstraction** to display the submenu.
3. Point to **Abstract Protocol**, and then click **Assign Reviewers**. The Assign Reviewers screen appears.

Entering New Data in the Assign Reviewers Screen

The Document Type, Document Number, Local Document Number, Review Type, Phase, Current Status, Title text boxes, and the Document Version(s) and Document Reviews fields pre-populate with data within the database.

1. Select the appropriate entries for Reviewer Name, Reviewer Role, and Lead Reviewer under Document Reviewers.
2. Enter the Date Distribution Packet Sent and Date Comments/Packet Received. You may also select the dates from the calendar.
3. Scroll to the right to display the Reviewer Comments Electronic File field. Click Browse to locate the electronic file. Click **Open File** to view the file.
4. Click the **Save** icon on the toolbar to save the information on the screen.

   A message appears on the status bar stating:

   Transaction complete: # records applied and saved.

Section 6 Revisions and Amendments

Revisions and Amendments

Since Letters of Intent and Concept Reviews amendments in their processes, this chapter applies only partially to those documents.

Revisions and Amendments Screen

The purpose of this screen (shown in Figure 30) is to track the revisions and amendments made to the protocol.

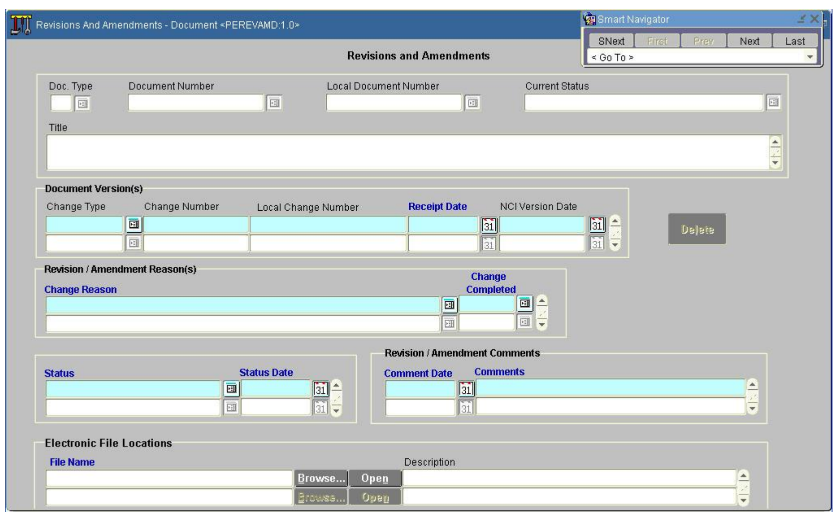
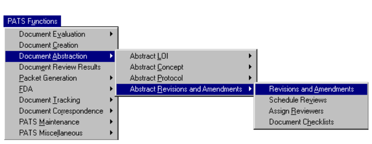


Figure 30 Revisions and Amendments Screen



Accessing the Revisions and Amendments Screen

1. From the Main menu, open the **PATS Functions**.
2. Point to **Document Abstraction** to display the submenu.
3. Point to **Abstract Revisions and Amendments**, and then click **Revisions and Amendments**. The Revisions and Amendments screen appears.

Entering New Data in the Revisions and Amendments Screen

1. The Document Type, Document Number, Local Document Number, Current Status, and Title text fields pre-populate based on the information already entered.
2. Select the Change Type of either Revision or Amendment.
3. Enter the Local Change Number of the change type selected in Step 1.
4. Enter the Receipt Date and Local Date of the Change Type.

   The system automatically assigns the Change Number on saving the information.

   Every Change Type must have its corresponding Change Reason to save a record into the database.

   The status of the Change Type defaults to In Review and the Status Date corresponds to the Receipt Date under Revision/Amendment.
5. Record any comments under Revisions/Amendments.
6. If the revision/amendment is submitted electronically, the same can be entered under Electronic File Location.
7. Once a change, that is, revision/amendment has been approved, the system automatically takes you to the affected screens as a result of the change. However, this feature does not work for the change reasons that have the word “manual” in them. These changes have to be done manually.

   Approved status has to be entered under Revision/Amendment status after fulfilling the criteria to approve the revision/amendment.
8. Once the change has been completed, change the Completed Flag in change reasons section to Yes. Make this change only if the Completed Flag displays No.

Schedule Reviews

Schedule Reviews Screen

The purpose of this screen (shown in Figure 31) is to schedule documents for review.

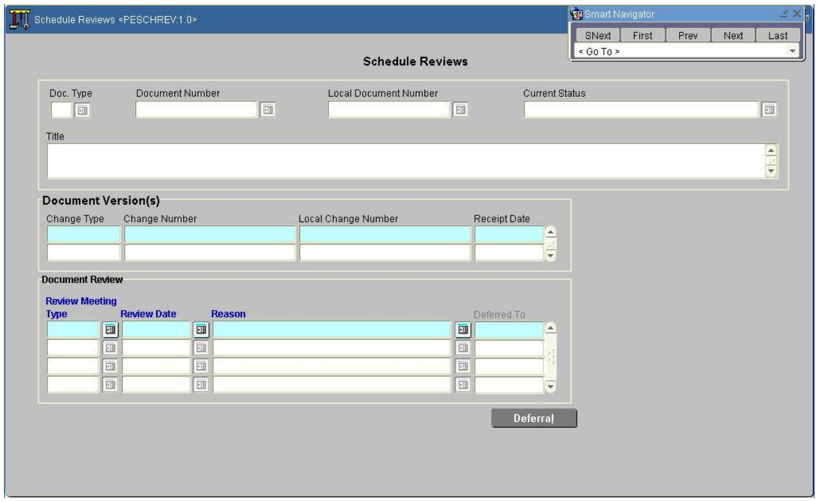
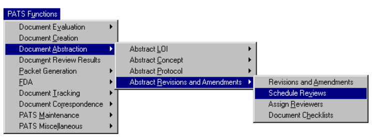


Figure 31 Schedule Reviews Screen

Accessing the Schedule Reviews Screen



1. From the Main menu, open **the PATS Functions** menu.
2. Point to **Document Abstraction** to display the submenu.
3. Point to **Abstract Revisions and Amendments**, and then click **Schedule Reviews**. The Schedule Reviews screen appears.

Entering New Data in the Schedule Reviews Screen

The Document Type, Document Number, Local Document Number, Current Status, and Title text fields pre-populate based on the information already entered.

1. Select the entries for Document Type, Document Number, and Current Status fields.
2. Click the **Execute Query** button from the toolbar. The Document Version(s) and Document Review regions pre-populate.
3. Select the appropriate entries for Review Meeting Type, Review Meeting Date, and Reason.
4. Click the **Save** icon on the toolbar to save the information on the screen. The user is given the option to change the review dates prior to completing this step.

   A message appears on the status bar stating:

   Transaction complete: # records applied and saved.

Assign Reviewers

Assign Reviewers Screen

The purpose of this screen (shown in Figure 32) is to assign reviewers for various reviews.

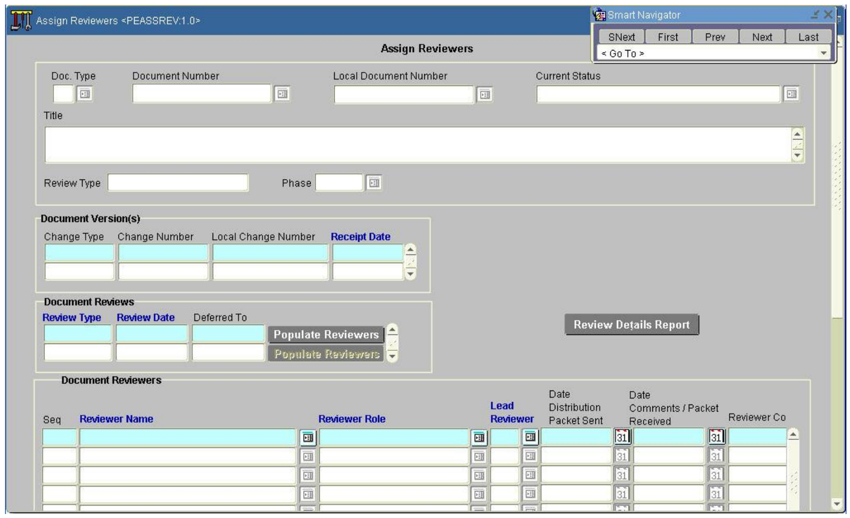
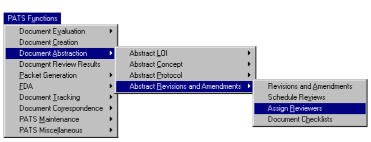


Figure 32 Assign Reviewers Screen

Accessing the Assign Reviewers Screen



1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Abstraction**, to display the submenu.
3. Point to **Abstract Revisions and Amendments**, and then click **Assign Reviewers**. The Assign Reviewers screen appears.

Entering New Data in the Assign Reviewers Screen

1. The Document Type, Document Number, Local Document Number, Review Type, Phase, Current Status, Title text boxes and the Document Version(s) and Document Reviews regions pre-populate with data from the database.
2. Select the appropriate entries for the Reviewer Name, Reviewer Role, and Lead Reviewer fields under Document Reviewers.
3. Enter the Date Distribution Packet Sent and Date Comments/Packet Received. You may also select the dates from the calendar.
4. Scroll to the right to display the Reviewer Comments Electronic File field. Click **Browse** to locate the electronic file. Click **Open File** to view the file.
5. Click the **Save** icon on the toolbar to save the information on the screen.

   A message appears on the status bar stating:

   Transaction complete: # records applied and saved.

Section 7 Document Review Results

Document Review Results

Document Review Results Screen

The purpose of this screen (shown in Figure 33) is to abstract scientific result, informed consent, and deferral information.

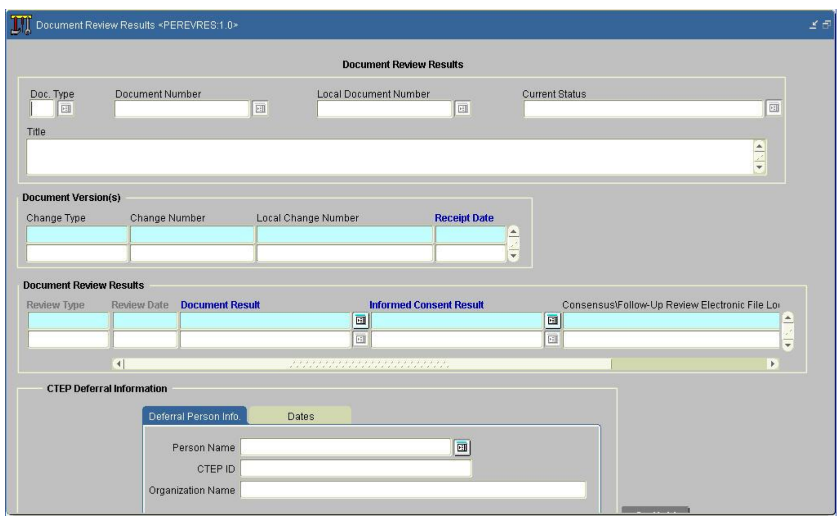
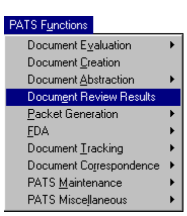


Figure 33 Document Review Results Screen



Accessing the Document Review Results Screen

1. From to the Main menu, open the **PATS Functions** menu.
2. Click **Document Review Results**. The Document Review Results screen appears.

Entering New Data in the Document Review Results Screen

The Document Type, Document Number, Local Document Number, Current Status, and Title text fields pre-populate based on the information already entered.

1. Select or enter ‘P’ in the Document Type field. Press the **Tab** button to advance to the next field.
2. Select or enter the appropriate information in the Document Number field.
3. Select or enter the appropriate information in the Scientific Result, Informed Consent Result, and Consensus Review Electronic File Location fields. Scroll to the right to display the **Browse** and **Open File** buttons. Use these buttons to assist you in locating the Consensus Review Electronic File.
4. Select the appropriate response for the Person Name in the CTEP Deferral Information section.

   The Person Name, CTEP ID, and Organization Name text boxes populate.

   Note that in order to enter deferral information, the Scientific Results field must have Deferred entered in it.
5. Click the Dates tab to display Deferral Date fields. Select the Date Deferred and New CTEP Date from the calendar, or enter the dates. Enter the Reason for the Deferral in the text field.

   The system automatically schedules the review using the New CTEP date.
6. Click the **On Hold** button. Refer to page 18 for instructions for completing the On Hold screen.
7. Click the **Save** icon on the toolbar to save the information on the screen.

   A message appears on the status bar stating:

   Transaction complete: # records applied and saved.

Section 8 Tracking Wizard

Tracking Wizard

Letters of Intent and Concept Reviews do not employ the Tracking Wizard.

The Tracking Wizard serves to assist you in tracking the Document Review process. As a document makes its way through the review process, you will record those events on the Milestones screen. When you need to report on the review process, you will access the Tracking Wizard screen (shown in Figure 34).

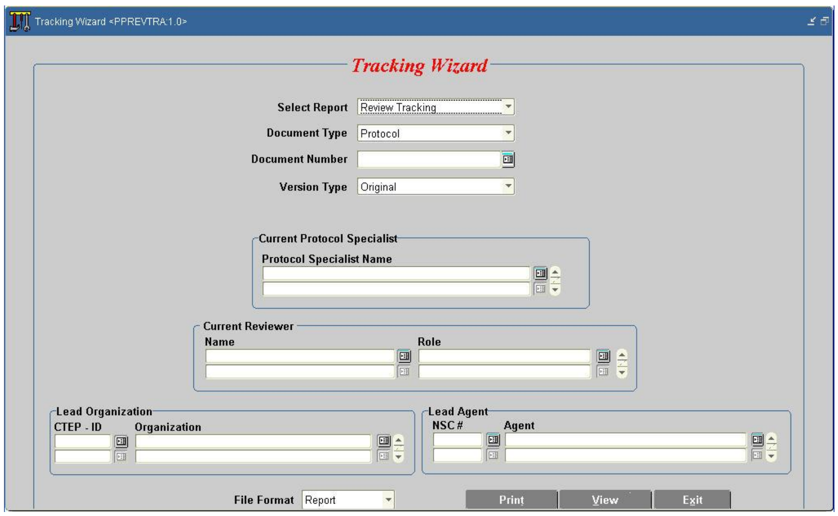


Figure 34 Tracking Wizard Screen

Generating a Report Using the Tracking Wizard

1. Select **Tracking Wizard** from the Main menu.

   The Tracking Wizard screen displays.

2. Select the Report you want to generate.

You have four report options.

Review Tracking	Provides a report on the milestones in the document review process. The system pulls the entries you make on the Milestones screen and reports them out for the documents meeting the query criteria you entered on the Tracking Wizard screen.
72 Hr. Tickler	Tracks how long reviewers have a document in their possession. Normally, reviewers should return a document in 72 hours (3 business days). You enter the date the document is sent to the reviewer in the Milestone screen. If the document is not returned and recorded on the Milestone screen, 72 hours later it will show up on the 72 Hr. Tickler Report.
Real Time Tickler	Tracks the same information as the 72 Hr. Tickler, but there is no time delay before the information displays on the report.
Timeline	Records all events entered on the Milestone screen, not just steps in the review process.

The report content depends on the criteria you select for inclusion.

3. Select as many report criteria as you want.

   You can select a specific Protocol number. Then the Tracking Wizard generates a report exclusively on that document.

   You can select all the Protocols managed by a specific Protocol Specialist. Then the Tracking Wizard generates a more extensive report.

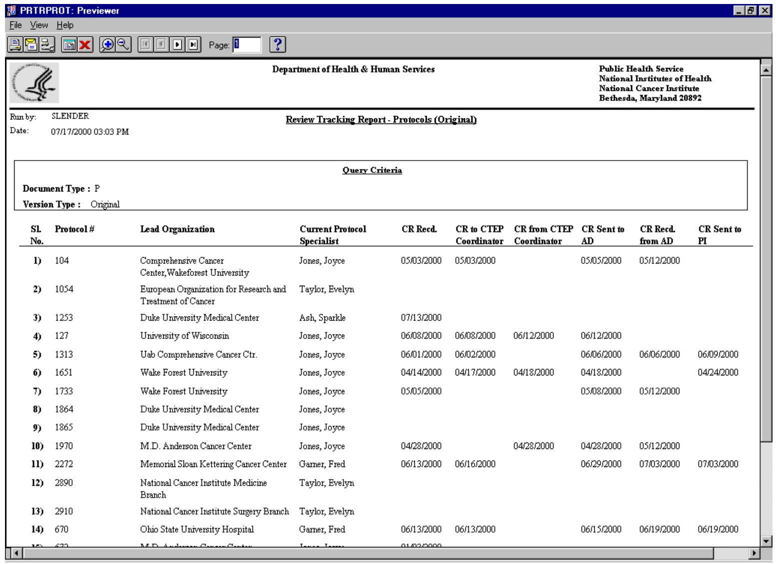
   When you select Amendment as the Version Type an additional field displays for you to enter the Amendment Number.

   When you select Timeline as the Report, the Reviewer fields disappear from the screen display.

4. Select the File Format you want to generate, either Report or PDF.

   You will select PDF when you want to save the report as a file. If you save the report as a PDF, you then have it in a format you can e-mail to other individuals.

5. Click on **View** to display your report to the screen (see Figure 35).



PRTRPROT: Previewer

File View Help

Page: 1

Department of Health & Human Services

Public Health Service
National Institutes of Health
National Cancer Institute
Bethesda, Maryland 20892

Run by: SLENDER
Date: 07/17/2000 03:03 PM

Review Tracking Report - Protocols (Original)

Query Criteria

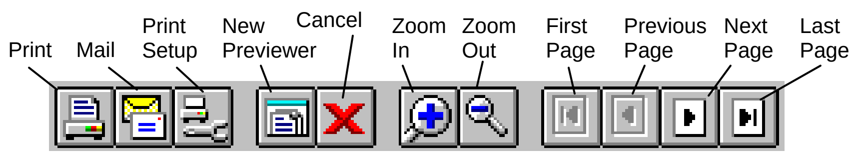
Document Type : P
Version Type : Original

Sl. No.	Protocol #	Lead Organization	Current Protocol Specialist	CR Recd.	CR to CTEP Coordinator	CR from CTEP Coordinator	CR Sent to AD	CR Recd. from AD	CR Sent to PI
1)	104	Comprehensive Cancer Center,Wakeforest University	Jones, Joyce	05/03/2000	05/03/2000		05/05/2000	05/12/2000	
2)	1054	European Organization for Research and Treatment of Cancer	Taylor, Evelyn						
3)	1253	Duke University Medical Center	Ash, Sparkle	07/13/2000					
4)	127	University of Wisconsin	Jones, Joyce	06/08/2000	06/08/2000	06/12/2000	06/12/2000		
5)	1313	Uab Comprehensive Cancer Ctr.	Jones, Joyce	06/01/2000	06/02/2000		06/06/2000	06/06/2000	06/09/2000
6)	1651	Wake Forest University	Jones, Joyce	04/14/2000	04/17/2000	04/18/2000	04/18/2000		04/24/2000
7)	1733	Wake Forest University	Jones, Joyce	05/05/2000			05/08/2000	05/12/2000	
8)	1864	Duke University Medical Center	Jones, Joyce						
9)	1865	Duke University Medical Center	Jones, Joyce						
10)	1970	M.D. Anderson Cancer Center	Jones, Joyce	04/28/2000		04/28/2000	04/28/2000	05/12/2000	
11)	2272	Memorial Sloan Kettering Cancer Center	Garner, Fred	06/13/2000	06/16/2000		06/29/2000	07/03/2000	07/03/2000
12)	2890	National Cancer Institute Medicine Branch	Taylor, Evelyn						
13)	2910	National Cancer Institute Surgery Branch	Taylor, Evelyn						
14)	670	Ohio State University Hospital	Garner, Fred	06/13/2000	06/13/2000		06/15/2000	06/19/2000	06/19/2000

Figure 35 Review Tracking Report

Once you display the report on the screen, you can print it out by clicking the **Print** toolbar button.

Notice that toolbar buttons unique to the Tracking Wizard display.



6. Click the **Print** button to send your report to the printer.

Section 9 Packet Generation

PRC Packet Generation

PRC Packet Generation Screen

The purpose of this screen (shown in Figure 36) is for the user to select the documents based on review date for generating the PRC Packet. The contents of the packet depend on the Document Type, Change Type, and Review Type. The table at the end of this section details the contents for the different PRC packets.

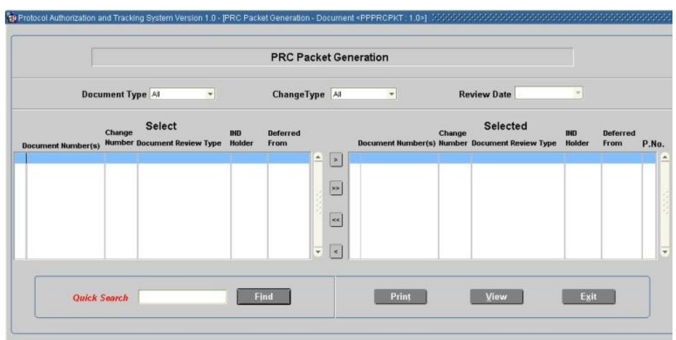
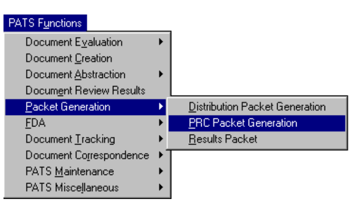


Figure 36 PRC Packet Generation Screen



Accessing the PRC Packet Generation Screen

1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Packet Generation**, and then click **PRC Packet Generation**.

Entering New Data in the PRC Packet Generation Screen

1. Select Protocol in the Document Type text field.
2. Select the appropriate response in the Change Type text field.
3. Select the appropriate response in the Review Date field.
4. The Select list shows all protocols in the system.

5. Highlight a specific protocol and click the click the greater than symbol (>) to move the protocol from the Select list to the Selected list.
6. Decide whether to view the report or send it to the printer.

   To print the report, click the **Print** button.

   To view the report, click the **View** button.

   The following table details the packet contents for each Change and Review Type associated with the different Document Types.

Document Type	**Change Type**	**Review Type**	**Packet Contents (in the stated order)**
Protocol	Original	PRC	PRC Agenda (listing all original documents) Document Quick Reference Reviewers Comments
	Revision	PRC	PRC Agenda (listing all revisions) Document Quick Reference Reviewers Comments
	Amendment	PRC	PRC Agenda (listing all amendments) Document Quick Reference Reviewers Comments
Letter of Intent	Original	PRC	PRC Agenda (listing all original documents) Document Quick Reference Reviewers Comments
	Revision	PRC	PRC Agenda (listing all revisions) Document Quick Reference Reviewers Comments
Concept Review	Original	PRC	PRC Agenda (listing all original documents) Document Quick Reference Reviewers Comments
	Revision	PRC	PRC Agenda (listing all revisions) Document Quick Reference Reviewers Comments

Section 10 FDA

FDA Letters

Letters of Intent and Concept Reviews do not include FDA letters.

FDA Screen

The purpose of this screen (shown in Figure 37) is to generate the new protocol or Amendment letter necessary to go the FDA.

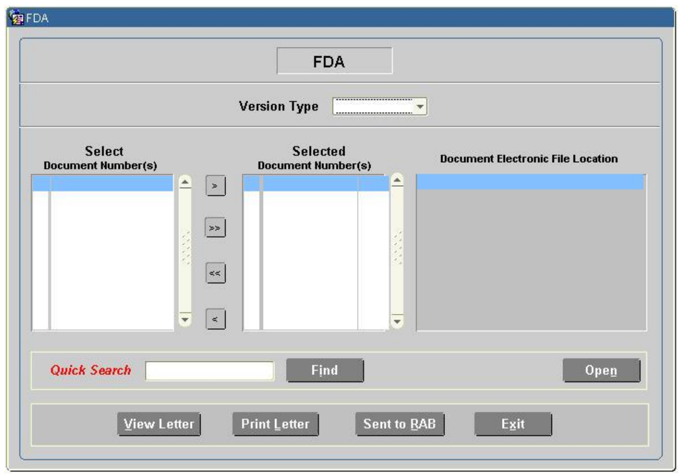
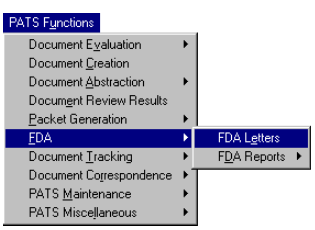


Figure 37 FDA Letters Screen



Accessing the FDA Screen

1. From the Main menu, open the **PATS Functions** menu.
2. Point to **FDA**, and then click **FDA Letters**. The FDA screen appears.

Entering New Data in the FDA Letters Screen

1. Select either New Protocol or Amendment in the Version Type text field.

   The Select list shows all Protocols in the system for which FDA letters can be generated.

2. Highlight a specific protocol and click the arrow (>) button to move the protocol from the Select list to the Selected list.

   In order to more several documents at once, select the documents, then click the double arrow (>>) button.

3. Decide whether to view the letter or send it to the printer.

   To print the letter, click the **Print** button.

   To view the letter, click the **View** button.

FDA Reports

Protocols/Amendments to be sent to FDA Screen

The purpose of this screen (shown in Figure 38) is to generate a report of all Protocols/Amendments that must be sent to FDA.

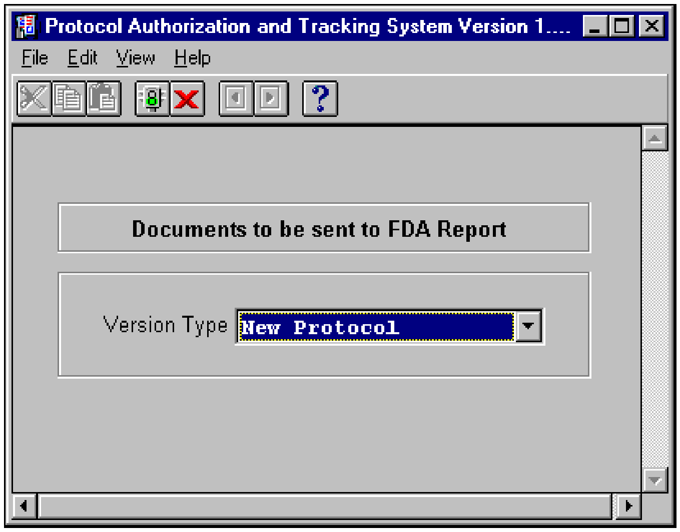
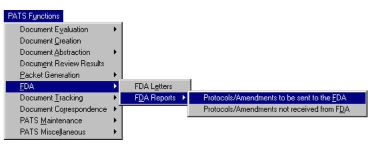


Figure 38 Protocols/Amendments to be sent to FDA Screen

Accessing the Protocols/Amendments to be sent to FDA Screen



1. From the Main menu, open the **PATS Functions** menu.
2. Point to **FDA** to display the submenu.
3. Point to **FDA Report**, and then click **Protocols/Amendments to be sent to FDA**. The Protocols/Amendments to be sent to FDA screen appears.

Entering New Data in the Protocols/Amendments to be sent to the FDA Screen

1. Select either New Protocol or Amendment in the Version Type text field.
2. Click the **Run Repor**t button on the tool bar.
3. Decide whether to view the report or send it to the printer.

   To print the report, click the **Print** button.

   To view the report, click the **View** button.

Section 11 Document Tracking

Document Received But Not Scheduled for PRC

Documents that were received but not scheduled for PRC Screen

Letters of Intent and Concept Reviews do not include the Document Tracking screens.

The purpose of this screen (shown in Figure 39) is to generate reports of protocol documents received but not yet scheduled for PRC Review.

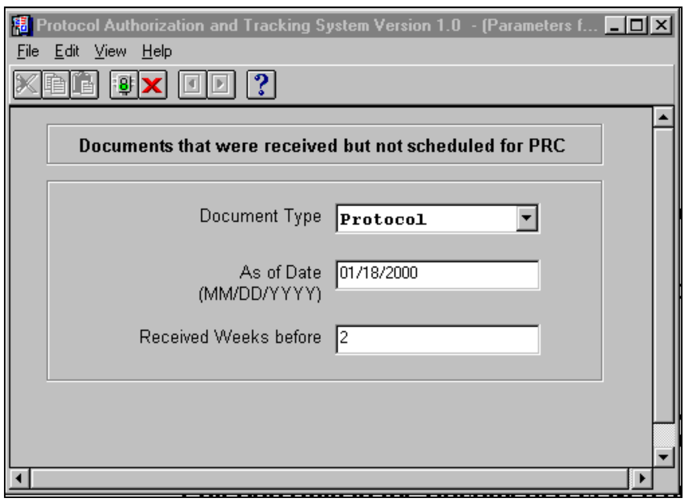
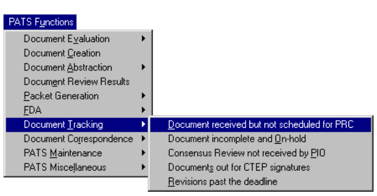


Figure 39 Documents that were received but not scheduled for PRC Screen

Accessing the Documents that were received but not scheduled for PRC Screen



1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Tracking**, and then click **Document received but not scheduled for PRC Report**. The Documents that were received but not scheduled for PRC Report screen appears.

Entering New Data in the Documents that were received but not schedule for PRC Screen

1. Select Protocol in the Document Type text field.

2. Enter the earliest date for which information should be included in the designated text field. Be sure to type the date in the MM/DD/YYYY format as shown.
3. Enter the number of weeks before this report to be included in this report in the designated text field. The default is two weeks.
4. Click the **Run Report** button on the toolbar to generate this report.
5. Decide whether to view the report or send it to the printer.

   To print the report, click the **Print** button.

   To view the report, click the **View** button.

Documents Out for CTEP Signature

Consensus Reviews out for CTEP Signature Report Screen

The purpose of this screen (shown in Figure 40) is to generate reports of consensus reviews that are out for CTEP signature.

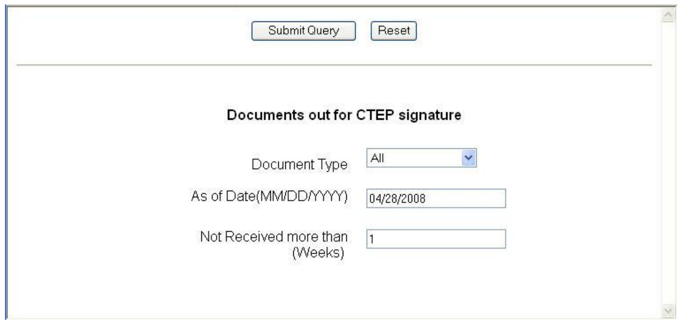
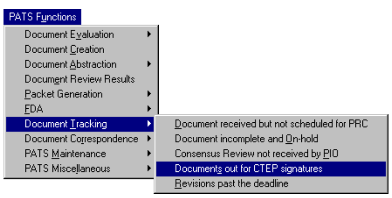


Figure 40 Consensus Reviews out for CTEP signature Report Screen

Accessing the Consensus Reviews out for CTEP signature Report Screen



1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Tracking**, and then click **Documents out for CTEP signatures**. The Consensus Reviews out for CTEP signatures Report screen appears.

Entering New Data in the Consensus Reviews out for CTEP signature Report Screen

1. Select Protocol in the Document Type text field.
2. Enter the earliest date for which information should be included in the designated text field. Be sure to type the date in the MM/DD/YYYY format as shown.
3. Enter the Not received more than (Weeks) to be included in this report in the designated text field.
4. Click the **Run Report** button on the toolbar to generate this report.
5. Decide whether to view the report or send it to the printer.

   To print the report, click the **Print** button.

   To view the report, click the **View** button.

Revisions Past the Deadline

Revisions past the deadline Report Screen

The purpose of this screen (shown in Figure 41) is to generate reports of revisions requested that have passed the deadline date and have not been received by the Protocol Information Office.

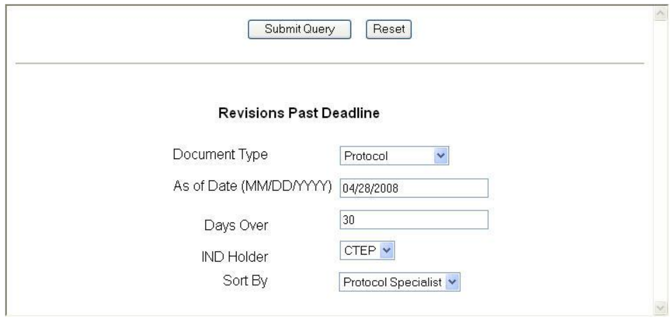
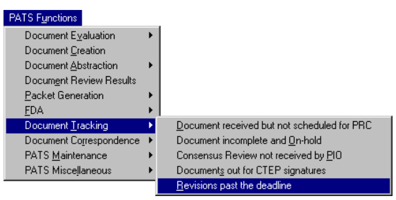


Figure 41 Revisions Past the Deadline Report Screen

Accessing the Revisions past the deadline Report Screen



1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Tracking**, and then click **Revisions past the deadline**. The Revisions past the deadline Report screen appears.

Entering New Data in the Revisions past the deadline Report Screen

1. Select Protocol in the Document Type text field.
2. Type the earliest date for which information should be included in the designated text field. Be sure to type the date in the MM/DD/YYYY format as shown.
3. Type the Deadlines Days in the designated text field.
4. Click the **Run Report** button on the toolbar to generate this report.
5. Decide whether to view the report or send it to the printer.

   To print the report, click the **Print** button.

   To view the report, click the **View** button.

Section 12 Document Correspondence

Acknowledgement Letters

Acknowledgement Letters Screen

The purpose of this screen (shown in Figure 42) is to select the document number for generating the complete or incomplete Acknowledgement letter.

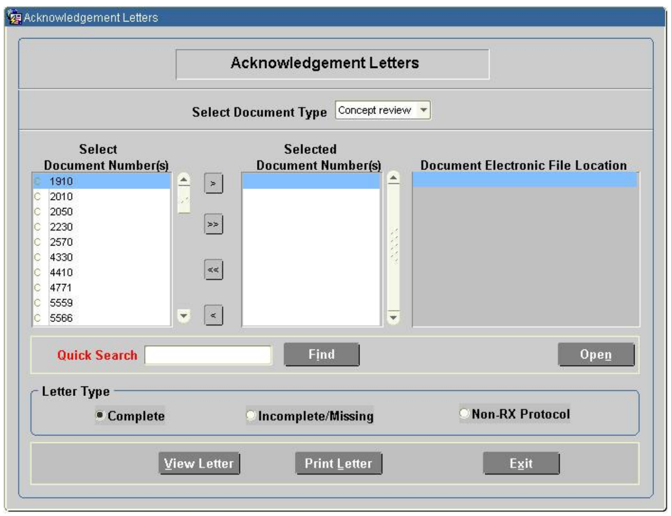
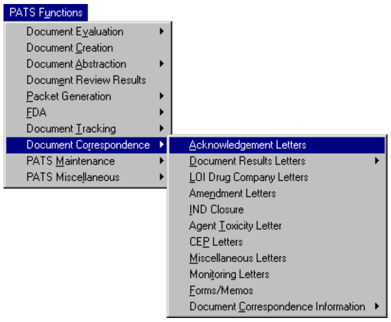


Figure 42 Acknowledgement Letters Screen



Accessing the Acknowledgement Letters Screen

1. From the Main menu, open the **PATS Functions** menu.

2. Point to **Document Correspondence**, and then click **Acknowledgement Letters**. The Acknowledgment Letters screen appears.

Entering New Data in the Acknowledgement Letters Screen

You may generate a single Acknowledgement Letter and have it printed, or you may generate multiple letters in one-step.

1. Select Protocol in the Document Type text field.

   The Select list shows all protocols in the system for which acknowledgement letters can be generated.

2. Highlight a specific protocol and click the click the arrow (>) button to move the protocol from the Select list to the Selected list.

   In order to more several documents at once, select the documents, then click the double arrow (>>) button.

   You can use the Quick Search feature to locate a document easily. Enter the document number, and then click on **Find**. The document display at the top of the Select list.

4. Select a document and click **Open** in order to access the document itself. You can make changes to the document at this point.

5. Click the **Complete** or **Incomplete/Missing** option button to choose the type of letter to be generated.

6. Decide whether to view the letter or send it to the printer.

   To print the letter, click the **Print** button.

   To view the letter, click the **View** button.

Document Results Letter

Document Results (Protocol) Screen

The purpose of this screen (shown in Figure 43) is to select the document number for generating the document results letter.

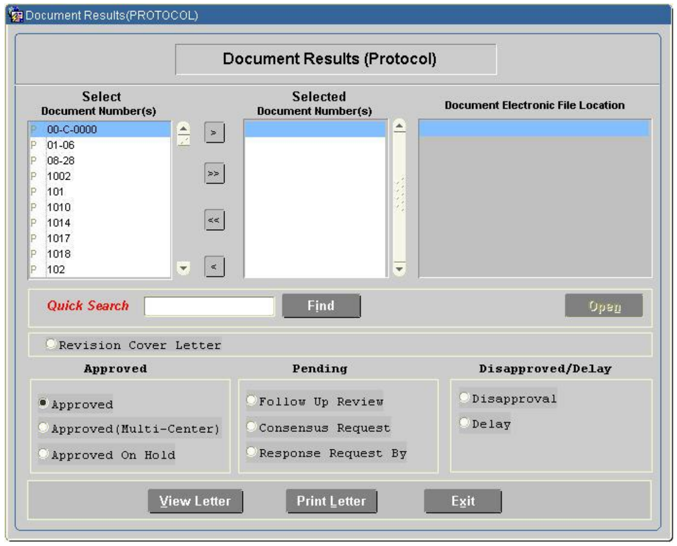
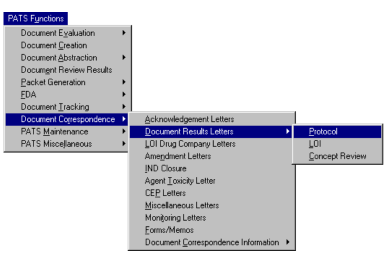


Figure 43 Document Results (Protocol) Screen

Accessing the Document Results (Protocol) Screen



1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Correspondence** to display the submenu.
3. Point to **Document Results Letter**, and then click **Protocol**. The Document Results (Protocol) screen appears.

Entering New Data in the Document Results (Protocol) Screen

You may generate a single Document Results Letter and have it printed, or you may generate multiple letters in one-step.

1. Select Protocol in the Document Type text field and choose Protocol.

   The Select list shows all Protocols in the system for which result letters can be generated.
2. Highlight a specific protocol and click the arrow (>) button to move the protocol from the Select list to the Selected list.

   In order to more several documents at once, select the documents, then click the double arrow (>>) button.
3. Click button for New, Delay, Approved, and Drug Approved to choose the type of letter to be generated.

4. Decide whether to view the letter or send it to the printer.
   To print the letter, click the **Print** button.
   To view the letter, click the **View** button.

Amendment Letters

Since Letters of Intent and Concept Reviews do not allow for amendments, Amendment Letters are not part of these modules.

Amendments Screen

The purpose of this screen (shown in Figure 44) is to generate correspondence regarding Amendments.

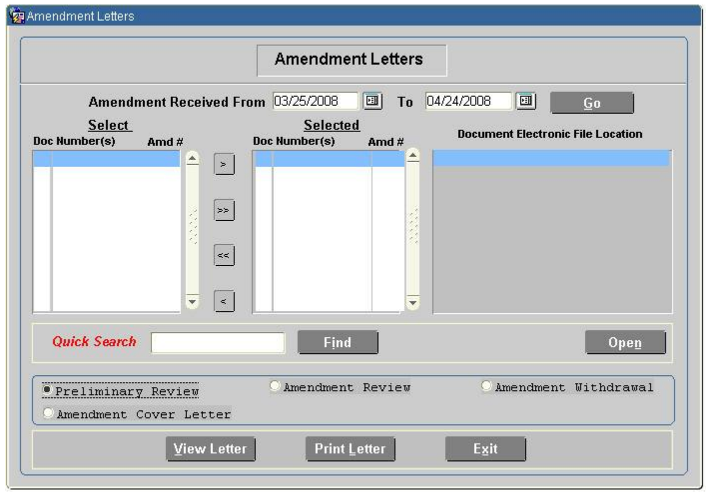
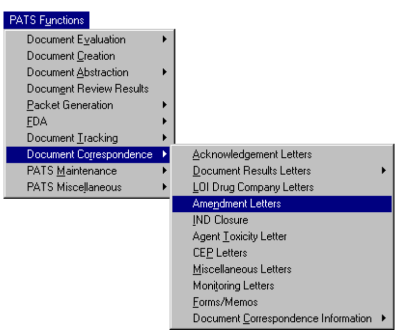


Figure 44 Amendments Screen



Accessing the Amendments Screen

1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Correspondence**, and then click **Amendment Letters**. The Amendments screen appears.

Entering New Data in the Amendments Screen

1. Highlight a specific Document Number and its Amendment and click the arrow (>) button to move it from the Select list to the Selected list.

   In order to more several documents at once, select the documents, then click the double arrow (>>) button.

2. Click button for New, Delay, Approved, and Drug Approved to choose the type of letter to be generated.
3. Decide whether to view the letter or send it to the printer.

   To print the letter, click the **Print Letter** button.

   To view the letter, click the **View Letter** button.

Concept Evaluation Panel Letters

These letters are used only for Concept Reviews. They are not part of a Protocol or Letter of Intent.

Concept Evaluation Panel Letters Screen

Concept Evaluation Panel letters serve to notify organizations of the action taken on concept proposals they have submitted. This screen (shown in Figure 45) provides the means to generate these letters.

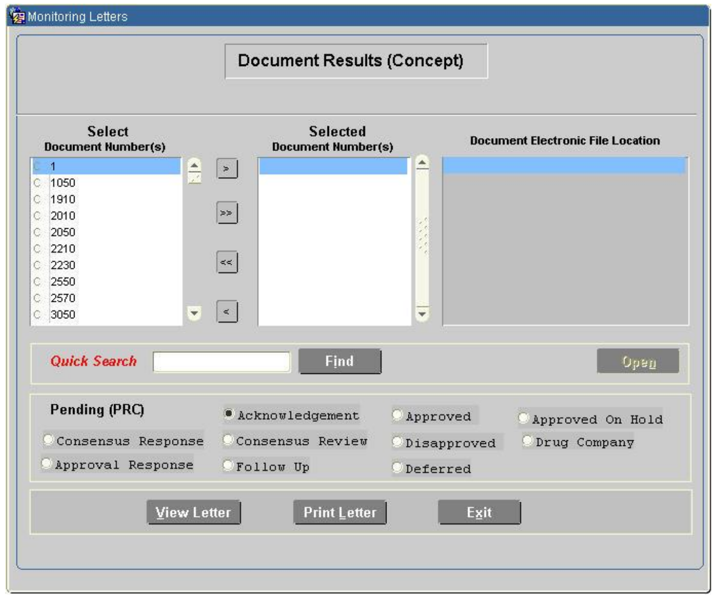
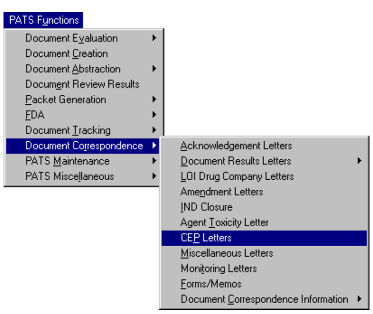


Figure 45 Concept Evaluation Panel Letters Screen

Accessing the Concept Evaluation Panel Letters Screen



1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Correspondence**, and then click **CEP Letter**. The Concept Evaluation Panel Letter screen appears.

Entering New Data in the Concept Evaluation Panel Letters Screen

You will select the Concept Review document(s), indicate the CEP decision on this concept proposal, and print out the letters.

You may generate a single letter and have it printed, or you may generate multiple letters in one-step.

1. Highlight a specific document number and click the arrow (>) button to move it from the Select list to the Selected list.

   In order to more several documents at once, select the documents, then click the double arrow (>>) button.

2. Choose the appropriate circle next to the Pending, Approved, or Disapproved category for which the letter should be generated.

3. Decide whether to view the letter or send it to the printer.

   To print the letter, click the **Print** button.

   To view the letter, click the **View** button.

Miscellaneous Letters

Miscellaneous Letters Screen

The purpose of this screen (shown in Figure 46) is to generate miscellaneous letters.

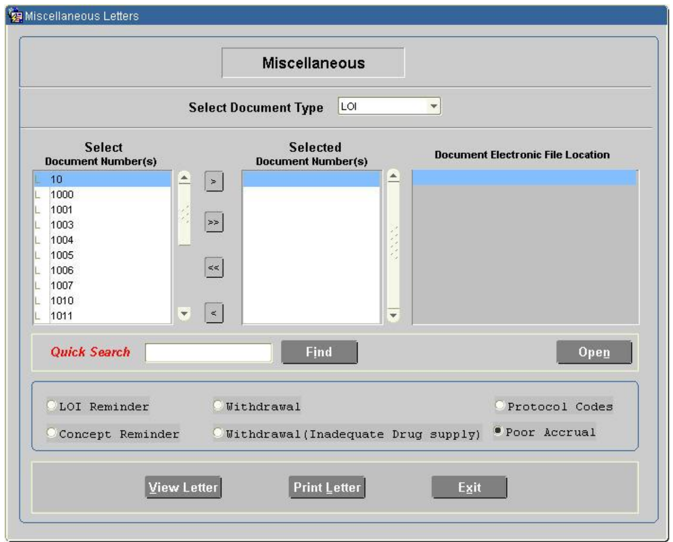
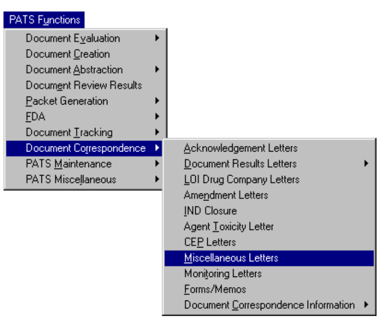


Figure 46 Miscellaneous Letters Screen



Accessing the Miscellaneous Letters Screen

1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Correspondence**, and then click **Miscellaneous Letter**. The Miscellaneous Letter screen appears.

Entering New Data in the Miscellaneous Letters Screen

You may generate a single letter and have it printed, or you may generate multiple letters in one-step.

1. Select Protocol in the Document Type field.

   The Select Document Number(s) list shows all applicable documents that can be generated.
2. Highlight a specific protocol and click the arrow (>) button to move the protocol from the Select list to the Selected list.

   In order to more several documents at once, select the documents, then click the double arrow (>>) button.
3. Choose the appropriate circle next to the Protocol Pending, Poor Accrual, Withdrawal, and Withdrawal (Inadequate Drug supply) categories for which the report should be generated.
4. Decide whether to view the letter or send it to the printer.

   To print the letter, click the **Print** button.

   To view the letter, click the **View** button.

Document Correspondence Information – Linked Correspondence

Document Correspondence Screen

The purpose of this screen (shown in Figure 47) is to record and track correspondence linked to a particular protocol.

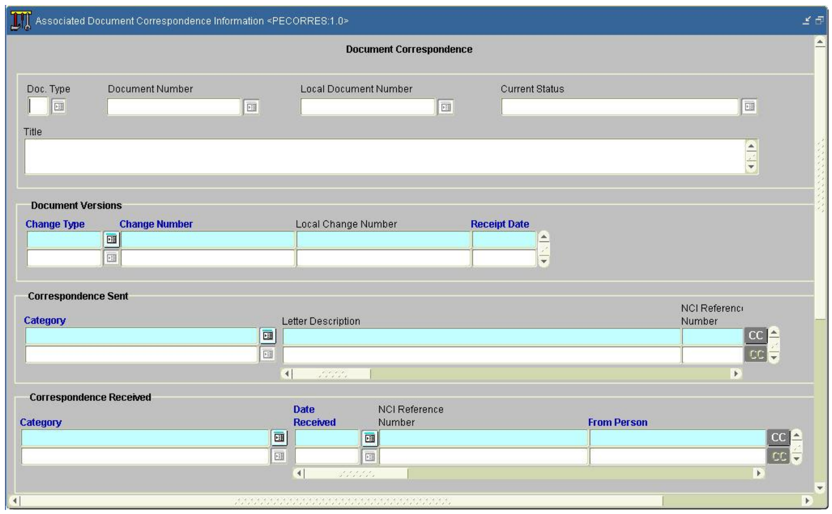
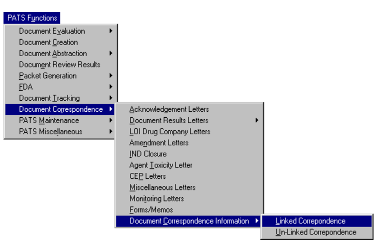


Figure 47 Document Correspondence Screen

Accessing the Document Correspondence Screen



1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Correspondence** to display the submenu.
3. Point to **Document Correspondence Information**, and then click **Linked Correspondence**. The Document Correspondence screen appears.

Entering New Data in the Document Correspondence Screen

You will use this screen to locate correspondence that is linked to other correspondence, such as, letters and responses with an organization. You will first locate the protocol document with which the correspondence is concerned. Then you can review the correspondence information or enter new information.

1. Click the **Enter Query** toolbar button.
2. Select or enter ‘P’ for Protocol in the Document Type field.
3. Select or enter the Document Number.
4. Click **Execute Query**.

   The Current Status, Title, and Document Versions fields populate. The Correspondence Sent fields populate with data that tracks all the correspondence sent out regarding this protocol.

5. Use the scroll bar for Correspondence Sent to view all the information related to any correspondence sent concerning this protocol.
6. Use the Correspondence Received section to add correspondence received that is related to the correspondence that has been sent out.

   The NCI Reference Number field is pre-populated identifying the correspondence received.
7. Enter any information concerning correspondence received that you need to record for this document. Be sure to scroll to the fields where you need to enter information.
8. Click the **Save** icon on the toolbar to save any information you have added or changed.

   A message appears on the status bar stating:

   Transaction complete: # records applied and saved.
9. Click the **Query Documents By Reference Number** button to locate a document, if you have the Reference Number, but not the Document number.

Document Correspondence Information – Unlinked Correspondence

Unassociated Correspondence Received

The purpose of this screen (shown in Figure 48) is to enter and track correspondence that does not fit a predetermined category related to the protocol.

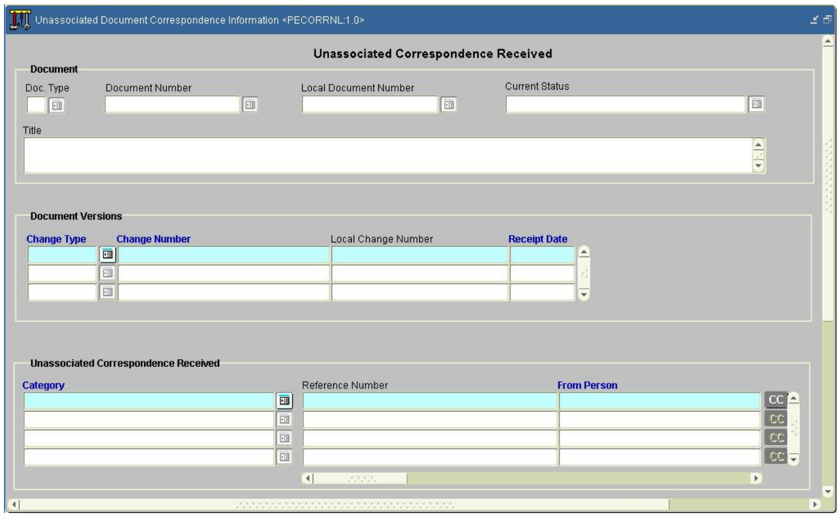
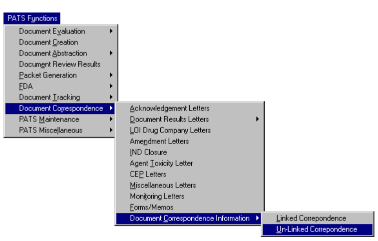


Figure 48 Unassociated Correspondence Received Screen

Accessing the Unassociated Correspondence Received Screen



1. From the Main menu, open the **PATS Functions** menu.
2. Point to **Document Correspondence** to display the submenu.
3. Point to **Document Correspondence Information**, and then click **Unlinked Correspondence**. The Unassociated Correspondence Received screen appears.

Entering New Data in the Unassociated Correspondence Received Screen

You will use this screen to locate correspondence that is not linked to other correspondence, such as, an inquiry from an organization. You will first locate the protocol document with which the correspondence is concerned. Then you can record the correspondence information.

1. Click the **Enter Query** toolbar button.
2. Select or enter ‘P’ for Protocol in the Document Type field.
3. Select or enter the Document Number.
4. Click **Execute Query**.

   The Title and Document Versions fields populate.

5. Select the Document Version to which the correspondence you are entering refers.
6. Select the Category for the correspondence you have received and want to record.
7. Enter the Reference Number. Select or enter the From Person, To Person, and the remaining information concerning this document. Use the scrollbar to access all the fields you need to use.
8. Click the **Save** icon on the toolbar to save the information on the screen.

   A message appears on the status bar stating:

   Transaction complete: # records applied and saved.

Section 13 Reports

Standard Reports

Following list details the Standard Reports you can generate through PATS. Reports available from submenus are listed under the menu option where they occur.

- Complete Sheet Report
  - Complete
- Document Quick Reference
- IDB Agenda
- LOIs waiting response from Drug Company
- Approved LOIs/Concept Reviews and No Protocols
- CTEP Agenda
  - Preliminary
  - Final
- Approved Documents
- Documents by Protocol Specialist

Tickler Reports

The following list details the Tickler Reports you can generate through PATS:

- Protocols awaiting PMB Approval
- Protocols awaiting Distribution approved by PMB
- Protocols waiting to be sent to PDQ
- Protocols signed and not sent to PMB
- Documents received and awaiting PRC
- Late List Report

Batch Reports

Batch Reports are those generated on a regular schedule. The following set of lists details the Batch Reports you can generate through PATS. They are divided by those generated weekly, fortnightly, monthly, bi-annually, and annually. Reports available from submenus are listed under the menu option where they occur.

Weekly Reports

Approved Revisions/Amendments for Documents

Approved Amendments for CTMS Protocols

Status Changes of Documents

Awaiting Consensus Reviews for Documents

CTEP Approved Documents On-Hold

Monthly Reports

Monthly Frequency

Counts by Document Decisions

Annual Reports

The only report generated on an annual basis is the Audit Report

Accessing and Generating the Reports

1. From the Main menu, open the **Reports** menu.
2. Point to **Standard**, **Tickler**, or **Batch** to display the appropriate submenu.
3. Click the report that you want to generate.

   The screen appropriate for the report you want to generate appears.

   For some of the reports you will need to enter an effective date for the report. For other reports you will have to select the specific documents you want included in the report.

   The Document Tracking section of this User’s Guide provides guidelines for generating many of the reports.